DEPARTMENT of DISTRUST

OPERATION WARP SPEED [OWS]

Operation Warp Speed

Official seal of Operation Warp Speed

Active	May 15, 2020 – February 24, 2021 (285 days)
Disbanded	Transitioned to White House COVID-19 Response Team
Country	United States
Allegiance	United States
Part of	U.S. Department of Defense U.S. Department of Health and Human Services Other various government agencies

According to the search results, the 8 companies that received funding of around $11 billion from Operation Warp Speed as of August 2020 to expedite development and preparation for manufacturing their COVID-19 vaccine candidates were:

1. Johnson & Johnson (Janssen Pharmaceutical) - $1 billion
2. AstraZeneca–University of Oxford and Vaccitech - $1.2 billion
3. Moderna - $1.5 billion
4. Novavax - $1.6 billion
5. Pfizer & BioNTech - $1.95 billion
6. Sanofi & GlaxoSmithKline - $2.1 billion
7. Regeneron - $450 million
8. Emergent BioSolutions - $628 million

The search results provide a comprehensive list of the 8 companies that received significant funding from Operation Warp Speed to accelerate the development and manufacturing of their COVID-19 vaccine candidates as of August 2020. 1 3 4

DoD + HHS

In total 8 companies were backed by OWS

OWS MCM Enterprise & Responsible Participants

OWS Injectables, therapies & other biological MCMs			
Drug Name(s):	**Manufacturers:**	**Market Status:**	**Involved Government Affiliations & Agencies:**
Remdesivir/Veklury	Gilead+ Ligand Pharmaceuticals	1st Use May 2020, Full Approval Oct 2020 All ages by April 2022	USAMRIID, NIH, UNC Chapel Hill, Univ AL, Vanderbilt, Columbia, DTRA, JSTO-CBD, DARPA
Lagevrio/ Molnupiravir	Merck +Ridgeback Bio	First Authorization Dec 2021	Emory DRIVE LLC
Paxlovid/ niratrelvir+ritonavir	Pfizer	Full Approval May 2023 First Use Dec 2021	
Bamlanivimab/LY-CoV555	Abcellera +Eli Lily	EUA Nov 2020,Renewed March 2021 Revoked April 2021	BMGF + DARPA's P3 Program [ADEPT]
Bebtelovimab	Abcellera +Eli Lily	EUA Feb 2022	Bill & Melinda Gates Foundation

Educational Institutions

Vanderbilt
UNC Chapel Hill
Univ. Penn
Univ TX Med Branch
Dartmouth
Emory
Univ. Alabama
Johns Hopkins
Georgetown

Non-Government Organizations

Bill & Melinda Gates Foundation [BMGF]
Scripps
CEPI
Wellcome Trust
EcoHealth Alliance
In-Q-Tel

Governmental Organizations

JPEO-CBRN [ARMY]
NIH/NIAID/FNIH
DARPA
DTRA
BARDA
ASPR/HHS
NSF
DHS-CWMD

Government Funded Medical Countermeasures through Operation Warp Speed

HTTPS://WWW.BECKERSHOSPITALREVIEW.COM/PHARMACY/13-DRUGMAKERS-CONTRACTED-BY-OPERATION-WARP-SPEED-IN-2020.HTML

1. **AstraZeneca** — In May, AstraZeneca signed a contract for $1.2 billion to boost access to its COVID-19 vaccine. In October, the drugmaker signed a second contract for $486 million for the U.S. to secure 100,000 doses of its experimental COVID-19 antibody drug and support clinical trials for the drug.

2. **Cytiva** — The Massachusetts drugmaker signed a contract in October for $31 million to scale up production of materials needed to produce COVID-19 vaccines, such as liquid and dry powder cell culture media, cell culture buffers, bioreactors and mixer bags.

3. **Eli Lilly** — In October, Eli Lilly signed a $375 million contract to supply 300,000 vials of its COVID-19 antibody drug, which was granted emergency authorization by the FDA in November. In early December, the drugmaker signed another $812.5 million contract to supply 650,00 more doses of the drug.

4. **Emergent BioSolutions** — In June, Emergent BioSolutions signed a $628 million contract to ramp up its contract development and manufacturing capabilities to expedite the delivery of COVID-19 vaccines.

5. **Fujifilm** — In July, Fujifilm signed a $265 million contract to manufacture COVID-19 vaccines.

6. **Johnson & Johnson** — In August, Johnson & Johnson signed a more than $1 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine if it is authorized.

Eli Lily: 1.1872B
AstraZeneca 1.68B
Emergent Bio: 628M
J&J: 1B
Moderna: 1.7B
Pfizer: 2B
GSK: 2.1B
Novavax: 1.6B

7. **Moderna** — In August, Moderna signed a $1.5 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.

8. **Novavax** — In July, Novavax signed a $1.6 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.

9. **Pfizer & BioNTech** — In July, Pfizer and BioNTech partnered to sign a $1.95 billion contract to supply up to 600 million doses of its COVID-19 vaccine. Under the contract, the U.S. would receive 100 million doses of the vaccine with the opportunity to secure 500 million more doses, but the U.S. did not secure the additional doses.

10. **Regeneron** — In July, Regeneron signed a $450 million contract to manufacture thousands of doses of its COVID-19 antibody cocktail, which was granted emergency authorization in November.

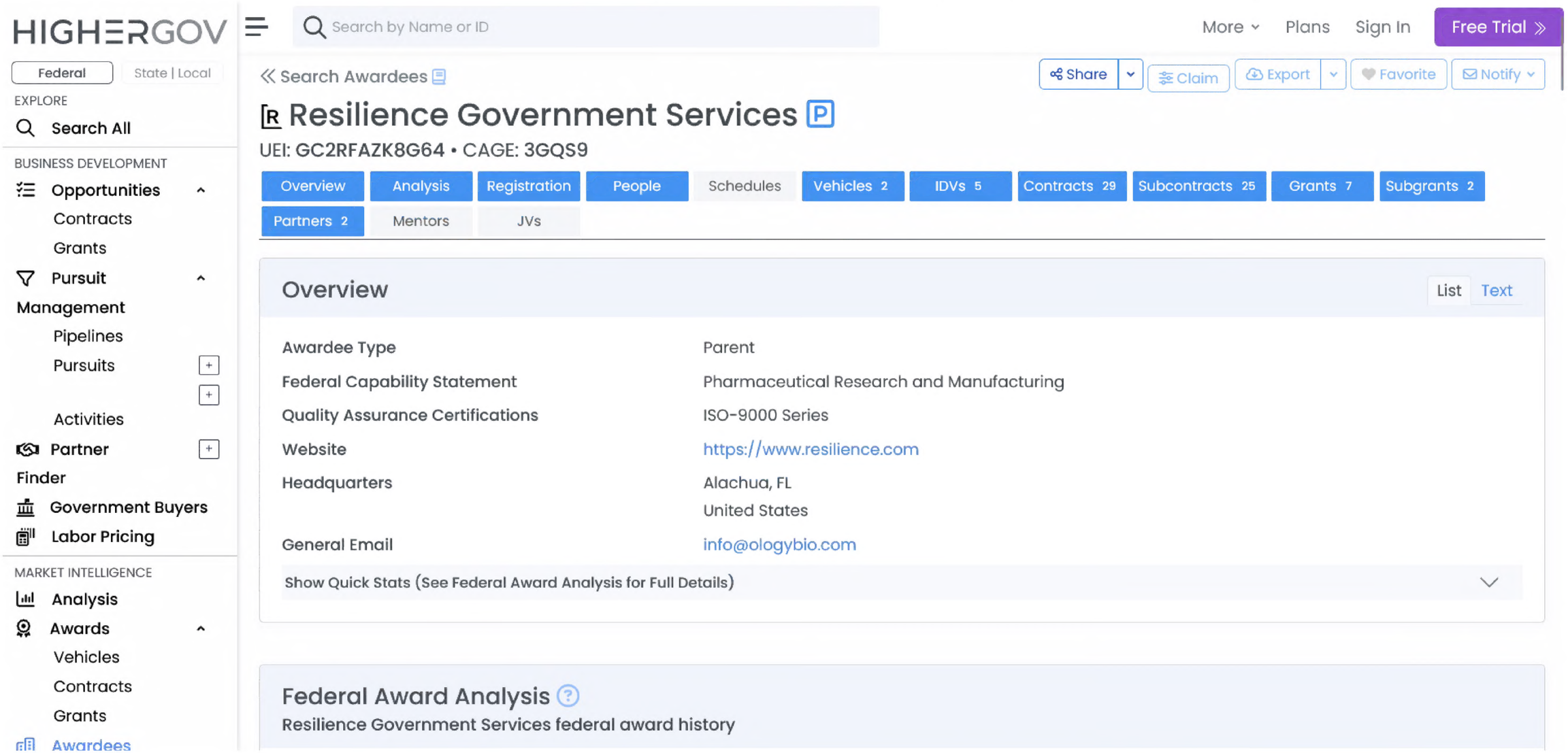
11. **Sanofi & GlaxoSmithKline** — In July, Sanofi and GlaxoSmithKline partnered to sign a $2.1 billion contract for development of the drugmaker's COVID-19 vaccine as well as an initial supply of 100 million doses.

Recipient Name	Start Date (Period of Performance)	End Date (Period of Performance)	Total Obligati Date
RESILIENCE GOVERNMENT SERVIC...	3/20/2013	3/20/2023	$276,824,216
RESILIENCE GOVERNMENT SERVIC...	8/17/2020	7/31/2021	$92,024,000
RESILIENCE GOVERNMENT SERVIC...	1/4/2022	2/29/2028	$86,818,905
RESILIENCE GOVERNMENT SERVIC...	9/28/2007	12/31/2011	$14,898,363
RESILIENCE GOVERNMENT SERVIC...	9/9/2019	8/11/2024	$14,408,703
RESILIENCE GOVERNMENT SERVIC...	8/15/2009	11/22/2013	$12,927,512
RESILIENCE GOVERNMENT SERVIC...	9/30/2013	6/29/2021	$10,604,966
RESILIENCE GOVERNMENT SERVIC...	3/22/2016	9/8/2021	$6,821,012
RESILIENCE GOVERNMENT SERVIC...	6/11/2015	6/10/2017	$6,193,052

Award ID	Recipient Name	Start Date (Period of Performance)	End Date (Period of Performance)	Total Obligations to Date
W911QY13C0010	RESILIENCE GOVERNMENT SERVIC...	3/20/2013	3/20/2023	$276,824,216
W911QY20C0101	RESILIENCE GOVERNMENT SERVIC...	8/17/2020	7/31/2021	$92,024,000
W911SR22F0014	RESILIENCE GOVERNMENT SERVIC...	1/4/2022	2/29/2028	$86,818,905
HHSN272200700030C	RESILIENCE GOVERNMENT SERVIC...	9/28/2007	12/31/2011	$14,898,363
75N93019C00057	RESILIENCE GOVERNMENT SERVIC...	9/9/2019	8/11/2024	$14,408,703
HHSN272200900015C	RESILIENCE GOVERNMENT SERVIC...	8/15/2009	11/22/2013	$12,927,512
HHSO10033001T	RESILIENCE GOVERNMENT SERVIC...	9/30/2013	6/29/2021	$10,604,966
HHSN272201600009C	RESILIENCE GOVERNMENT SERVIC...	3/22/2016	9/8/2021	$6,821,012
HHSO10033003T	RESILIENCE GOVERNMENT SERVIC...	6/11/2015	6/10/2017	$6,193,052
W911SR22F0073	RESILIENCE GOVERNMENT SERVIC...	6/16/2022	2/28/2025	$4,861,156
HHSO100201100047C	RESILIENCE GOVERNMENT SERVIC...	9/30/2011	12/15/2016	$4,808,836
HHSO10033004T	RESILIENCE GOVERNMENT SERVIC...	6/11/2015	6/9/2018	$4,761,491
W911SR23F0057	RESILIENCE GOVERNMENT SERVIC...	3/7/2023	1/5/2028	$4,502,407
HHSO10033002T	RESILIENCE GOVERNMENT SERVIC...	11/18/2014	10/31/2017	$3,251,785
HHSN266200500046P	RESILIENCE GOVERNMENT SERVIC...	9/29/2005	3/31/2010	$3,044,549
HHSN271200577414C	RESILIENCE GOVERNMENT SERVIC...	9/15/2005	6/30/2009	$892,166
W81XWH10C0245	RESILIENCE GOVERNMENT SERVIC...	9/1/2010	9/30/2013	$853,082
HHSN27200002	RESILIENCE GOVERNMENT SERVIC...	8/7/2017	2/3/2020	$816,089
W911QY19C0049	RESILIENCE GOVERNMENT SERVIC...	4/1/2019	7/31/2021	$722,220
N0001406C0043	RESILIENCE GOVERNMENT SERVIC...	11/14/2005	11/13/2007	$491,836
75N93023F00001	RESILIENCE GOVERNMENT SERVIC...	8/28/2023	5/30/2024	$485,288
HHSD200200302362C	RESILIENCE GOVERNMENT SERVIC...	9/4/2003	3/14/2004	$98,838
HHSN27200001	RESILIENCE GOVERNMENT SERVIC...	9/2/2016	8/31/2017	$11,645

$542,901,015

On Highergov, a government contract tracking website, shows the Definitive Contract W911QY13C0010 between the US ARMY & Resilience/Ology Bioservices. It not only shows the history of the contracts dated pre-pandmic, starting in 2013. It also shows that $4,361,774 of the Definitive Contract was funded by COVID-19 emergency acts including the CARES Act.



https://www.highergov.com/contract/W911QY13C0010/#people

Definitive Contract W911QY13C0010 between the US ARMY & Resilience/Ology Bioservices.

https://www.highergov.com/contract/W911QY13C0010/#people

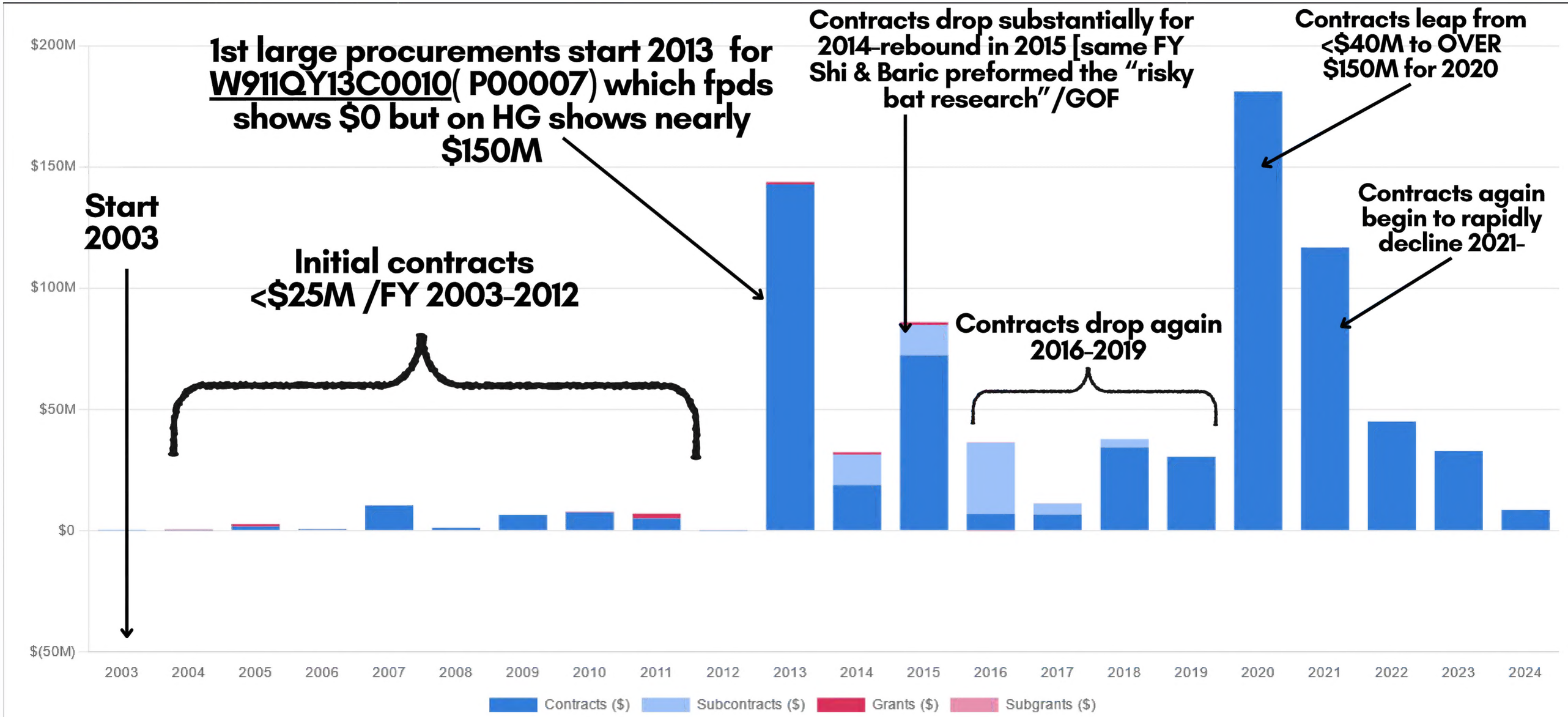
CARES ACT & OPERATION WARP SPEED

- The CARES Act provided funding for Operation Warp Speed.
- Operation Warp Speed was initially funded with about $10 billion from the CARES Act (Coronavirus Aid, Relief, and Economic Security) passed by the United States Congress on March 27, 2020.
- Congress directed almost $10 billion to Operation Warp Speed through supplemental funding, including the CARES Act. This included more than $6.5 billion designated for countermeasure development through BARDA and $3 billion for NIH research.
- In searching for funding, the Operation Warp Speed team pulled $10 billion from the CARES Act, which was there thanks to Treasury Secretary Steven Mnuchin, who had added extra money to the Strategic National Stockpile in order to create a slush fund.

In summary, the CARES Act provided a significant portion of the initial funding for Operation Warp Speed's efforts to accelerate the development and production of COVID-19 vaccines and treatments. The Act allocated over $10 billion specifically for this purpose.

Overview | Analysis | Registration | People | Schedules | Vehicles 2 | IDVs 5 | Contracts 29 | Subcontracts 25 | Grants 7 | Subgrants 2

Partners 2 | Mentors | JVs



https://www.highergov.com/contract/W911QY13C0010/#people

Definitive Contract W911QY13C0010 between the US ARMY & Resilience/Ology Bioservices.

Agency Detail

Awarding Office	W911QY W6QK ACC-APG NATICK
Funding Office	W56XNH
Created By	dan.l.adams2.civ@army.mil
Last Modified By	dan.l.adams2.civ@army.mil
Approved By	dan.l.adams2.civ@army.mil

Legislative

Legislative Mandates	Materials, Supplies, Articles & Equipment
Performance District	FL-03
Senators	Marco Rubio Rick Scott
Representative	Katherine Cammack

Budget Funding

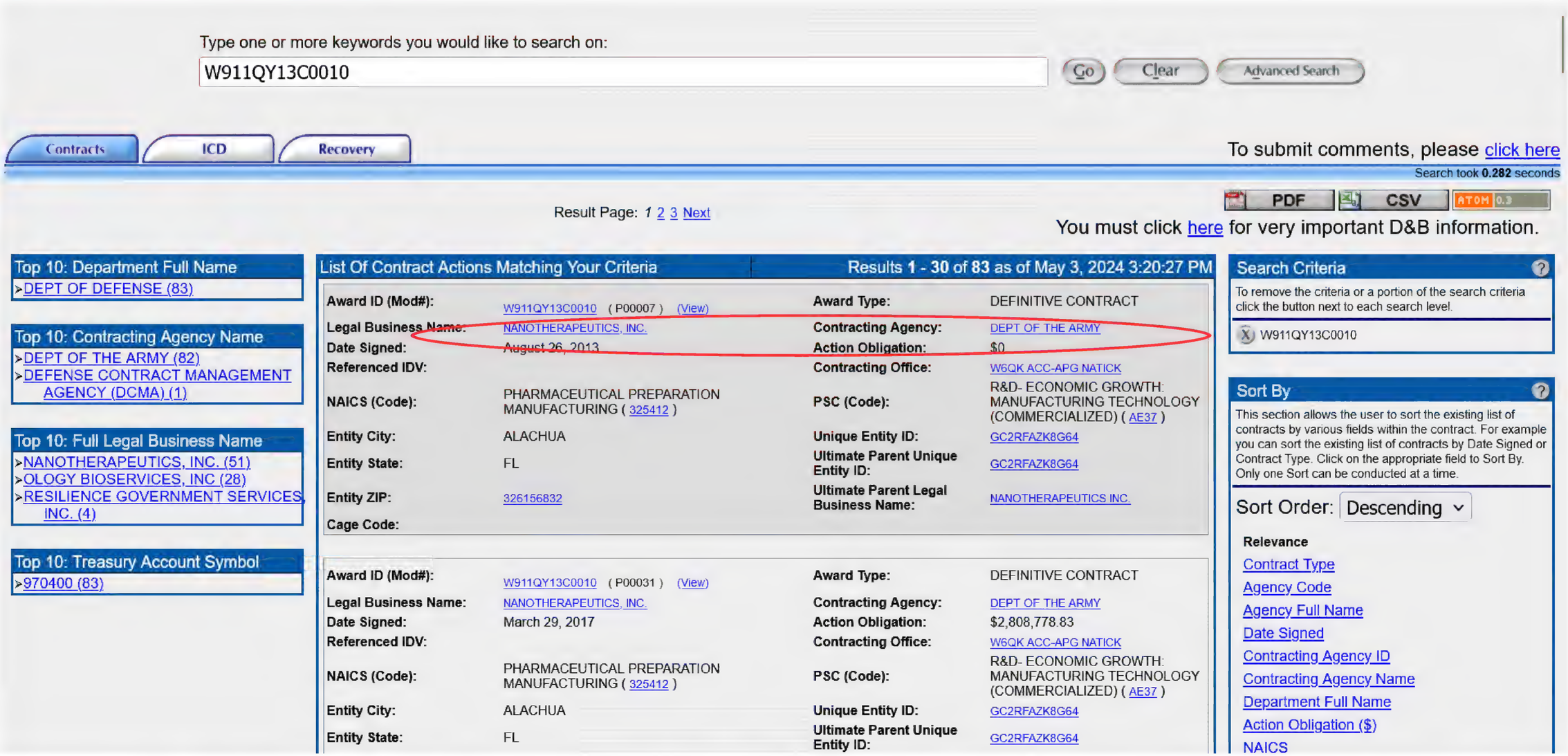
Federal Account	Budget Subfunction	Object Class	Total	Percentage
Research, Development, Test, and Evaluation, Defense-Wide (097-0400)	Department of Defense-Military	Research and development contracts (25.5)	$19,910,440	89%
Research, Development, Test, and Evaluation, Defense-Wide (097-0400)	Department of Defense-Military	Other services from non-Federal sources (25.2)	$2,464,858	11%

Definitive Contract W911QY13C0010 between the US ARMY & Resilience/Ology Bioservices.

A definitive contract is a mutually binding legal relationship that obligates the government to an expenditure of appropriated funds.

https://www.highergov.com/contract/W911QY13C0010/#people

On the Federal Procurement Data System [fpds.gov] , a government owned and operated contract tracking program it shows the Definitive Contract W911QY13C0010. Involved the Defense Contract Management Agency [DCMA], the US ARMY & the record shows : Resilience Government Services [4 contracts] Ology Bioservices [28 contracts] & Nanotherapeutics [51 contracts] For a total of 83 contracts between the entity called "Resilience" and the DoD.



https://www.fpds.gov/ezsearch/fpdsportal?indexName=awardfull&templateName=1.5.3&s=ICD&q=W911QY13C0010&x=0&y=0

According to HIGHERGOV, as detailed in the

Sep 2014:
Nanotherapeutics, Inc.,* Alachua, Florida was awarded a $9,647,917 modification (P00018) to contract W911QY-13-C-0010 for Medical Countermeasures (MCM) Advanced Development and Manufacturing (ADM) capability for rapid development of countermeasures against chemical, biological, radiological, and nuclear attacks and outbreaks of naturally occurring and genetically engineered infectious diseases. Fiscal 2014 research, development, testing, and evaluation funds in the amount of $9,647,917were obligated at the time of the award. Estimated completion date is March 19, 2015. Work will be performed in Alachua, Florida. Army
Contracting Command, Natick, Massachusetts is the contracting activity. (Awarded Sept. 28, 2014).

May 2015: Nanotherapeutics Inc.,* Alachua, Florida, was awarded a $43,249,906 modification (P00020) to contract W911QY-13-C-0010 for research and development of medical countermeasures and their manufacture to counter a chemical, biological, radiological, nuclear and explosives attack against military and civilian targets. Work will be performed in Alachua, Florida, with an estimated completion date of Aug. 15, 2016. Fiscal 2014 research, development, testing, and evaluation funds in the amount of $4,324,906 were obligated at the time of the award. Army Contracting Command, Natick, Massachusetts, is the contracting activity.

Sep 2019: Ology Bioservices Inc.,* Alachua, Florida, was awarded a $10,870,944 modification (P00054) to contract W911QY-13-C-0010 to establish, commission and support an agile and flexible advanced development and manufacturing capability. Work will be performed in Alachua, Florida, with an estimated completion date of March 19, 2023. Fiscal 2020 research, development, test and evaluation funds in the amount of $7,845,964 were obligated at the time of the award. U.S. Army Contracting Command, Aberdeen Proving Ground, Maryland, is the contracting activity.

Dec 2019: Ology Bioservices Inc., Alachua, Florida, was awarded an $8,553,208 modification (P00058) to contract W911QY-13-C-0010 to support the Medical Countermeasures Advanced Development and Manufacturing Center Sustainment by maintaining the Advanced Development and Manufacturing facility in a state of readiness and operational availability to develop, test and/or manufacture medical countermeasures. Work will be performed in Alachua, Florida, with an estimated completion date of March 19, 2023. Fiscal 2021 research, development, test and evaluation, defense-wide funds in the amount of $8,553,208 were obligated at the time of the award. U.S. Army Contracting Command, Aberdeen Proving Ground, Natick Division, Natick, Massachusetts, is the contracting activity.

https://www.highergov.com/contract/W911QY13C0010/#people

List Of Contract Actions Matching Your Criteria — Results 1 - 30 of 83 as of May 3, 2024 3:38:53 PM

Aug 2013 — $0

Award ID (Mod#):	W911QY13C0010 (P00007) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	NANOTHERAPEUTICS, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	August 26, 2013	Action Obligation:	$0
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING (325412)	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) (AE3T)
Entity City:	ALACHUA	Unique Entity ID:	GC2REAZ48964
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2REAZ48964
Entity ZIP:	326158832	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS, INC.
Cage Code:			

Mar 2017 — $2.8M

Award ID (Mod#):	W911QY13C0010 (P00031) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	NANOTHERAPEUTICS, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	March 29, 2017	Action Obligation:	$2,808,778.83
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING (325412)	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) (AE3T)
Entity City:	ALACHUA	Unique Entity ID:	GC2REAZ48964
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2REAZ48964
Entity ZIP:	326158726	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS, INC.
Cage Code:	3GQB9		

Oct 2017 — $2.5M

Award ID (Mod#):	W911QY13C0010 (P00038) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	NANOTHERAPEUTICS, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	December 06, 2017	Action Obligation:	$2,500,000
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING (325412)	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) (AE3T)
Entity City:	ALACHUA	Unique Entity ID:	GC2REAZ48964
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2REAZ48964
Entity ZIP:	326158726	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS, INC.
Cage Code:	3GQB9		

Jun 2018 — $2M

Award ID (Mod#):	W911QY13C0010 (P00043) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	NANOTHERAPEUTICS, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	June 12, 2018	Action Obligation:	$2,000,000
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING (325412)	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) (AE3T)
Entity City:	ALACHUA	Unique Entity ID:	GC2REAZ48964
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2REAZ48964
Entity ZIP:	326158726	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS, INC.
Cage Code:	3GQB9		

Sept 2019 — **$7.8M**

Award ID (Mod#):	W911QY13C0010 (P00054) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	OLOGY BIOSERVICES, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	September 10, 2019	Action Obligation:	$7,845,964.34
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING (325412)	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) (AE3T)
Entity City:	ALACHUA	Unique Entity ID:	GC2REAZ48964
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2REAZ48964
Entity ZIP:	326158726	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS, INC.
Cage Code:	3GQB9		

Transaction Information

Award Type:	Definitive Contract	**Prepared Date:**	03/28/2019 16:11:39	**Prepared User:**	LAWRENCE.MIZE.W911QY@US.ARMY.MIL
Award Status:	Final	**Last Modified Date:**	03/28/2019 16:11:43	**Last Modified User:**	LAWRENCE.MIZE.W911QY@US.ARMY.MIL
Closed Status:	No	**Closed Status Date:**		**Closed By:**	
		Approved Date:	03/28/2019 16:11:43	**Approved By:**	LAWRENCE.MIZE.W911QY@US.ARMY.MIL

Document Information

	Agency	*Procurement Identifier*	*Modification No*	*Trans No*
Award ID:	9700	W911QY13C0010	P00051	0
Referenced IDV ID:				
Reason For Modification:	EXERCISE AN OPTION			
Solicitation ID:	W911QY11R0023			

	Agency Identifier	*Main Account*	*Sub Account*	*Initiative*
Treasury Account Symbol:	97	0400		Select One

Dates

Date Signed *(mm/dd/yyyy)* **:**	03/28/2019
Period of Performance Start Date *(mm/dd/yyyy)* **:**	03/29/2019
Completion Date *(mm/dd/yyyy)* **:**	10/31/2020
Est. Ultimate Completion Date *(mm/dd/yyyy)* **:**	10/31/2023
Solicitation Date *(mm/dd/yyyy)* **:**	

Amounts

	Current	**Total**
Action Obligation:	$7,031,994.58	$276,824,216.28
Base And Exercised Options Value:	$12,379,190.00	$282,290,978.35
Base and All Options Value (Total Contract Value):	-$26,139,593.00	$366,290,602.35
Fee Paid for Use of IDV:	$0.00	

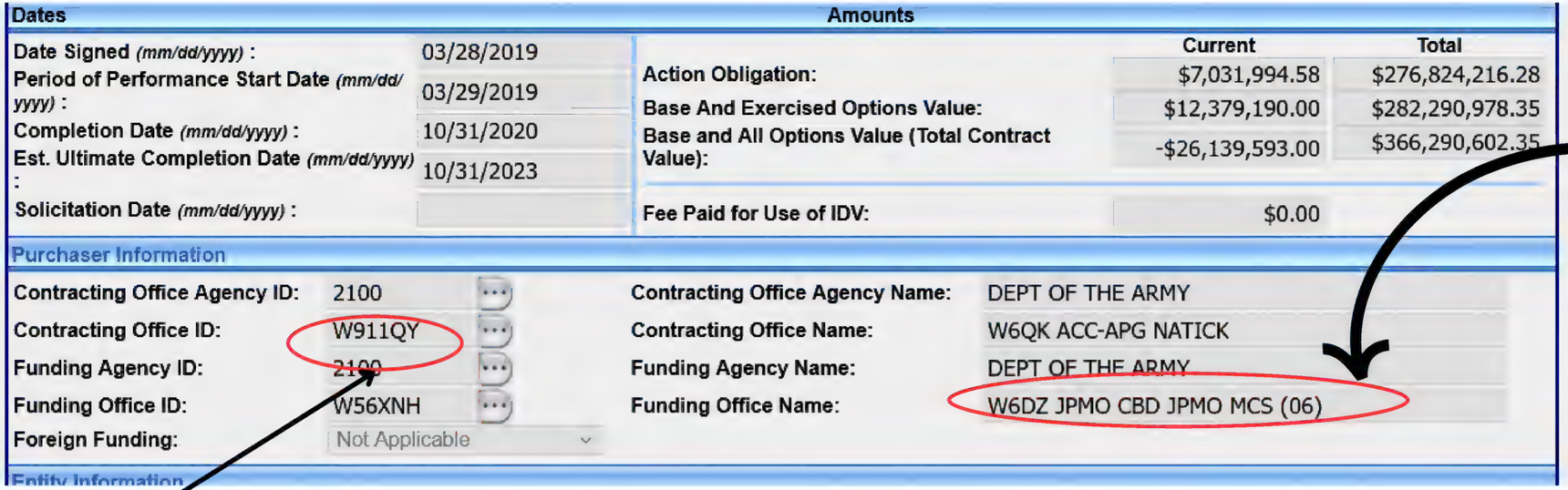
Purchaser Information

Contracting Office Agency ID:	2100	**Contracting Office Agency Name:**	DEPT OF THE ARMY
Contracting Office ID:	W911QY	**Contracting Office Name:**	W6QK ACC-APG NATICK
Funding Agency ID:	2100	**Funding Agency Name:**	DEPT OF THE ARMY
Funding Office ID:	W56XNH	**Funding Office Name:**	W6DZ JPMO CBD JPMO MCS (06)
Foreign Funding:	Not Applicable		

Entity Information

W911QY

W911QY refers to a series of contracts and solicitations related to the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND).The key details are:W911QY-20-C-0119 is a contract awarded to AstraZeneca Pharmaceuticals LP for $855 million to manufacture medical countermeasures. W911QY-18-D-0232 to W911QY-18-D-0252 are a set of multiple award Indefinite Delivery Indefinite Quantity (IDIQ) contracts for the JE-OPETS program, which provides Chemical, Biological, Radiological, and Nuclear (CBRN)-related program management and Systems Engineering and Technical Assistance (SETA) support.



Dates	
Date Signed *(mm/dd/yyyy)* :	03/28/2019
Period of Performance Start Date *(mm/dd/yyyy)* :	03/29/2019
Completion Date *(mm/dd/yyyy)* :	10/31/2020
Est. Ultimate Completion Date *(mm/dd/yyyy)* :	10/31/2023
Solicitation Date *(mm/dd/yyyy)* :	

Amounts	Current	Total
Action Obligation:	$7,031,994.58	$276,824,216.28
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Fee Paid for Use of IDV:	$0.00	

Purchaser Information

Contracting Office Agency ID:	2100	Contracting Office Agency Name:	DEPT OF THE ARMY
Contracting Office ID:	W911QY	Contracting Office Name:	W6QK ACC-APG NATICK
Funding Agency ID:	2100	Funding Agency Name:	DEPT OF THE ARMY
Funding Office ID:	W56XNH	Funding Office Name:	W6DZ JPMO CBD JPMO MCS (06)
Foreign Funding:	Not Applicable		

Entity Information

Funding Office Name:

W6DZ JPMO CBD JPMO MCS

W911QY

W6DZ JPMO CBD JPMO MCS (06) refers to the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), which is the funding office for several contracts related to chemical and biological defense programs.

W6DZ JPMO CBD JPMO MCS (06) is listed as the funding office for multiple contracts with Eli Lilly and Company totaling over $4.6 billion & for contract W911QY21C0016 with Eli Lilly and Company..

W6DZ JPMO CBD JPMO MCS (06) is mentioned as the parent award details for contract W911SR23F7017 with MURTECH, INC

It is also listed as the funding department for contract W15QKN21C0003 related to COVID-19 contracts.

W6DZ JPMO CBD JPMO MCS (06) is the funding office code for the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, which oversees various contracts **related to chemical and biological defense programs**

PLOS | NEGLECTED TROPICAL DISEASES

REVIEW

Zika Virus: Medical Countermeasure Development Challenges

Robert W. Malone[1,2]*, Jane Homan[3], Michael V. Callahan[4], Jill Glasspool-Malone[1,2], Lambodhar Damodaran[5], Adriano De Bernardi Schneider[5], Rebecca Zimler[6], James Talton[7], Ronald R. Cobb[7], Ivan Ruzic[8], Julie Smith-Gagen[9], Daniel Janies[5‡], James Wilson[10‡], Zika Response Working Group

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Citation: Malone RW, Homan J, Callahan MV, Glasspool-Malone J, Damodaran L, Schneider ADB, et al. (2016) Zika Virus: Medical Countermeasure Development Challenges. PLoS Negl Trop Dis 10(3): e0004530. doi:10.1371/journal.pntd.0004530

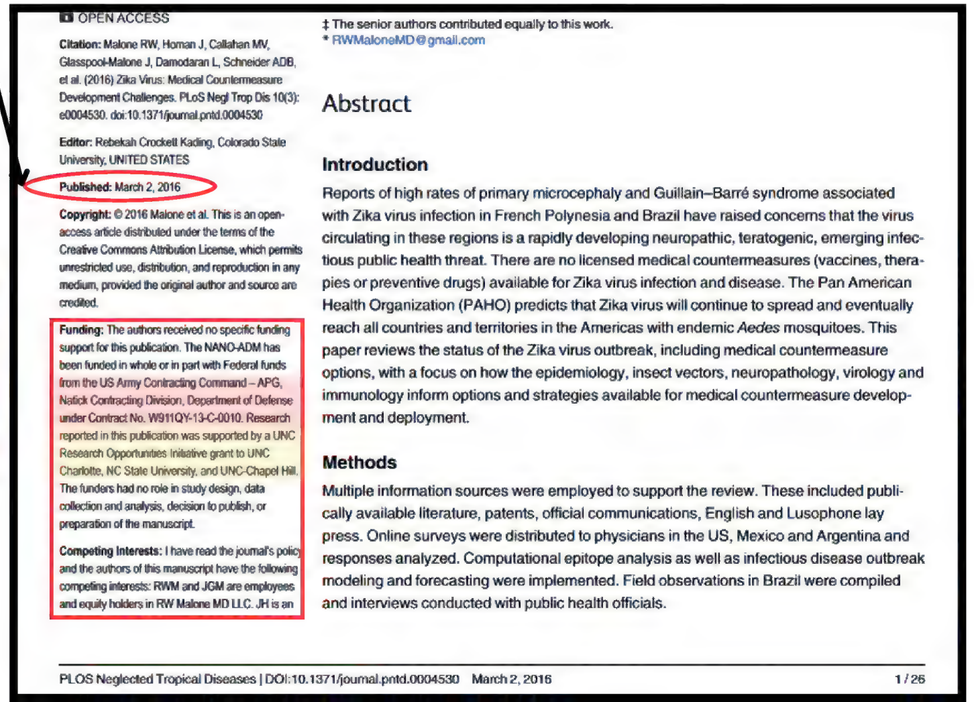
Editor: Rebekah Crockett Kading, Colorado State University, UNITED STATES

Abstract

Introduction

This 2016 paper, although it does not appear to be directly related to C19 in fact is. It is important to C19 for 5 reasons.

1. The Zika Virus research in 2016 helped the VRC in their work leading to their creation of the **C19 Vaccine w/Moderna** [2017]
2. A listed author is **Michael Callahan**, "**DARPA's Man in Wuhan**" whom fellow author, Robert Malone, claimed is CIA and that Callahan is "a very skilled liar."
3. Dr. Robert Malone [contractee of the DTRA] **inventor of the mRNA** "vaccine" platform & his wife Dr. Jill Glasspool-Malone are authors.
4. Two employees **[Talton+Cobb] of Nanotherapeutics [Resilience/Ology]** & acknowledges the JPEO-CBRND's ownership by identifying the DoD's name for the facility, NANO-ADM as the facility for Nanotherapeutics.. **The Funding itself shows it was on the dime of the Aberdeen Proving Grounds,** NATICK, of the US ARMY, the **SAME exact command** that ALL the C19 "vaccines" were contracted through.
5. Three of 13 authors are representing **UNC Chapel Hill**, who was undoubtedly the home to the world's most advanced coronavirus research[i.e Ralph Baric/Gillings School of Public health]



OPEN ACCESS

Citation: Malone RW, Homan J, Callahan MV, Glasspool-Malone J, Damodaran L, Schneider ADB, et al. (2016) Zika Virus: Medical Countermeasure Development Challenges. PLoS Negl Trop Dis 10(3): e0004530. doi:10.1371/journal.pntd.0004530

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Published: March 2, 2016

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Funding: The authors received no specific funding support for this publication. The NANO-ADM has been funded in whole or in part with Federal funds from the US Army Contracting Command – APG, Natick Contracting Division, Department of Defense under Contract No. W911QY-13-C-0010. Research reported in this publication was supported by a UNC Research Opportunities Initiative grant to UNC Charlotte, NC State University, and UNC-Chapel Hill. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: I have read the journal's policy and the authors of this manuscript have the following competing interests: RWM and JGM are employees and equity holders in RW Malone MD LLC. JH is an

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Abstract

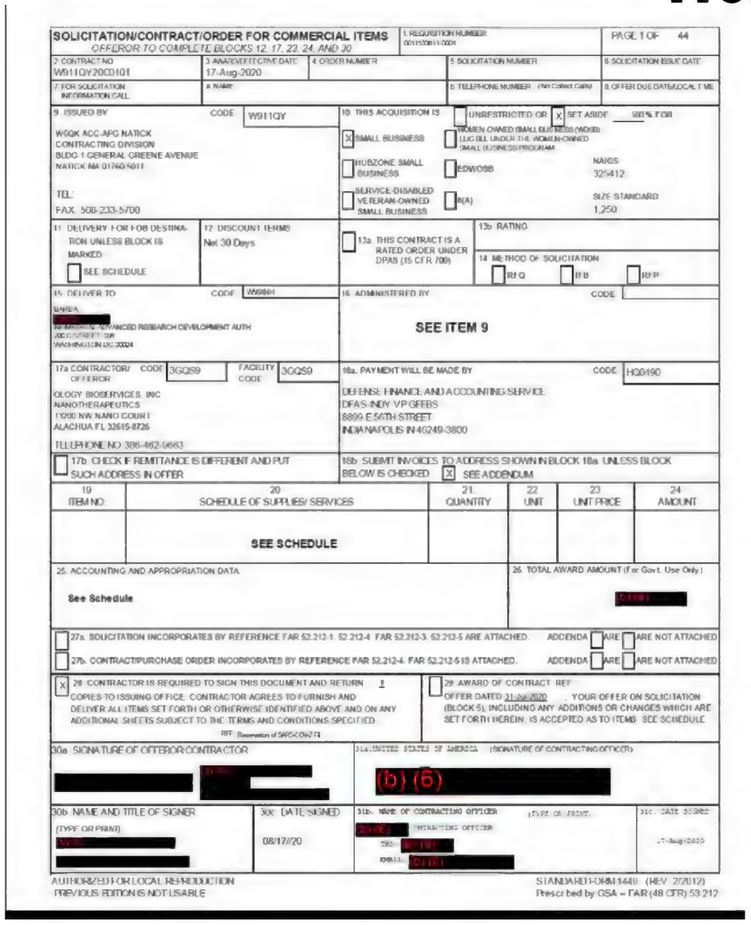
Introduction

Reports of high rates of primary microcephaly and Guillain–Barré syndrome associated with Zika virus infection in French Polynesia and Brazil have raised concerns that the virus circulating in these regions is a rapidly developing neuropathic, teratogenic, emerging infectious public health threat. There are no licensed medical countermeasures (vaccines, therapies or preventive drugs) available for Zika virus infection and disease. The Pan American Health Organization (PAHO) predicts that Zika virus will continue to spread and eventually reach all countries and territories in the Americas with endemic *Aedes* mosquitoes. This paper reviews the status of the Zika virus outbreak, including medical countermeasure options, with a focus on how the epidemiology, insect vectors, neuropathology, virology and immunology inform options and strategies available for medical countermeasure development and deployment.

Methods

Multiple information sources were employed to support the review. These included publically available literature, patents, official communications, English and Lusophone lay press. Online surveys were distributed to physicians in the US, Mexico and Argentina and responses analyzed. Computational epitope analysis as well as infectious disease outbreak modeling and forecasting were implemented. Field observations in Brazil were compiled and interviews conducted with public health officials.

W6DZ JPMO CBD JPMO MCS



SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS (OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30) — PAGE 1 OF 44

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
W911QY20D3101	17-Aug-2020			

7. FOR SOLICITATION INFORMATION CALL: — a. NAME — b. TELEPHONE NUMBER (NO Collect Calls) — 8. OFFER DUE DATE/LOCAL TIME

9. ISSUED BY — CODE W911QY
W6QK ACC-APG NATICK
CONTRACTING DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011
TEL:
FAX: 508-233-5700

10. THIS ACQUISITION IS: [ ] UNRESTRICTED OR [X] SET ASIDE: 100 % FOR
[X] SMALL BUSINESS — [ ] WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
[ ] HUBZONE SMALL BUSINESS — [ ] EDWOSB
[ ] SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS — [ ] 8(A)
NAICS: 325412
SIZE STANDARD: 1,250

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED: [ ] SEE SCHEDULE

12. DISCOUNT TERMS: Net 30 Days

13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION: [ ] RFQ [ ] IFB [ ] RFP

15. DELIVER TO — CODE W6BNH
NAMEA: [redacted]
[redacted] ADVANCED RESEARCH DEVELOPMENT AUTH
[redacted]
WASHINGTON DC 20024

16. ADMINISTERED BY — CODE
SEE ITEM 9

17a. CONTRACTOR/ OFFEROR — CODE 3GQS9 — FACILITY CODE 3GQS9
IOLOGY BIOSERVICES, INC
NANOTHERAPEUTICS
13200 NW NANO COURT
ALACHUA FL 32615-8726
TELEPHONE NO. 386-462-6663

18a. PAYMENT WILL BE MADE BY — CODE HQ0490
DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS-INDY VP GFEBS
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

[ ] 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED [X] SEE ADDENDUM

19 ITEM NO.	20 SCHEDULE OF SUPPLIES/ SERVICES	21 QUANTITY	22 UNIT	23 UNIT PRICE	24 AMOUNT
	SEE SCHEDULE				

25. ACCOUNTING AND APPROPRIATION DATA
See Schedule

26. TOTAL AWARD AMOUNT (For Govt. Use Only)
[redacted]

[ ] 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3. 52.212-5 ARE ATTACHED. ADDENDA [ ] ARE [ ] ARE NOT ATTACHED
[ ] 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA [ ] ARE [ ] ARE NOT ATTACHED

[X] 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.
REF: Reservation of SRSC0270

[ ] 29. AWARD OF CONTRACT: REF: OFFER DATED 31-Jul-2020. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE

30a. SIGNATURE OF OFFEROR/CONTRACTOR: [redacted]

31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER): (b) (6)

30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT): [redacted]

30c. DATE SIGNED: 08/17/20

31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT): [redacted] CONTRACTING OFFICER
TEL: [redacted]
EMAIL: [redacted]

31c. DATE SIGNED: 17-Aug-2020

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Prescribed by GSA – FAR (48 CFR) 53.212

ADM Report 2018
BARDA + JPEO-CBRND
ASPR + DOD

Published on 11-08-2018

https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf

https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf

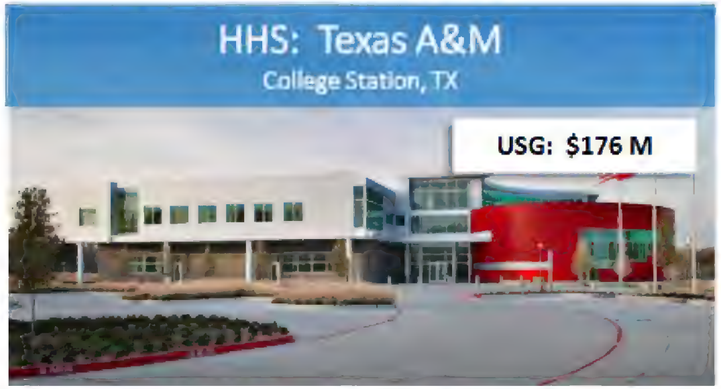
HHS CIADM REQUIREMENT

Centers for Innovation in Advanced Development and Manufacturing

Objectives

- Construct new or retrofitted facilities utilizing state-of-the-art flexible manufacturing approaches;
- Provide core services for the advanced development and manufacturing of CBRN biopharmaceutical countermeasures supported by the U.S. Government;
- Provide U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats; and
- Biopharmaceutical oriented workforce development through training programs aligned with current regulatory guidelines.

HHS AND DOD ADM INVESTMENTS



Total Base Period Capital Investment: $602 M

https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf

ADM TIGER TEAM
ACTIVITIES OVERVIEW

ADM Tiger Team Established

Michael Angelastro, BARDA Co-Lead
Timothy Belski, DoD Co-Lead
Keith Wells, Ph.D., BARDA SME
Mark Michalik, BARDA SME
Jean Hu-Primmer, FDA
Chris Southworth, DoD ADMC Support
Patricia Haigwood, BARDA CIADM Support
Barry Sayer, DoD ADMC Support

ADM Assessment Activities

Data Gathering

Discussions and Site Visits
- Emergent
- Ology
- Texas A&M
- Seqirus

Stakeholder Input / Landscape Analysis
- JVAP, JSTO
- PRISM
- DARPA
- SIP
- Biodefense Blue Ribbon Panel
- National Academies
- ASPR
- ASH
- WRAIR

Assessment of Key Inputs and Actions

Synthesis of Barriers and Potential Solutions

!?

Lists are not all inclusive

https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf

https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf

PARTNERSHIP GOALS

ADM MODEL	PARTNERSHIP APPROACH
• ADM facilities worked independently	• HHS and DOD will collaborate, create a 'whole of government approach'
• Funded industry partners were required to use ADM facilities for certain efforts	• HHS and DOD will work with industry to provide incentives to use ADM facilities
• Any IP and legal challenges were left to the ADM facilities and industry partners to work out	• All challenges (IP, legal issues, etc) will be worked on as a team with support from USG
• Product-focused	• The ADM facilities will have the capability to handle a broad array of threats with proven technologies such as cell lines, adjuvants, and monoclonal antibody technologies
• Specific, often rigid, funding vehicle	• Exploring alternate funding vehicles for ease of contracting for industry
• Challenges due to ADM facilities being constructed, staffed, standing up	• Construction of all ADM facilities are complete and staffed with experienced manufacturing personal

The Business Report

Nanotherapeutics Breaks Ground on New Facility in Alachua

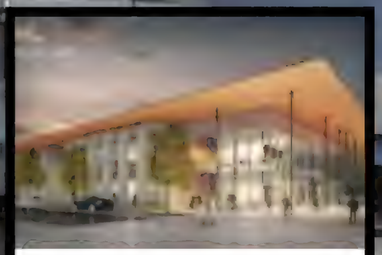
Posted by Business Report of North Central Florida Date: October 23, 2013 in: News

Nanotherapeutics, Inc., a biopharmaceutical company out of Alachua that began as a startup in the UF Sid Martin Biotech Incubator, held a groundbreaking to celebrate the start of construction on its new facility on Wednesday. In attendance were dozens of business and local government representatives, as well as Florida Gov. Rick Scott.

The new 165,000-square-foot facility at 13200 NW Nano Court — in Progress Corporate Park — is expected to completed and occupied by March 2015. The new construction is the result of a Department of Defense contract worth $135 million with the aim to reduce the overall time and cost associated with the development and manufacturing of medical countermeasures against chemical, biological, radiological and nuclear attacks and outbreaks of naturally occurring and genetically engineered infectious diseases.

The new facility will officially be called the Nanotherapeutics Advanced Development and Manufacturing Center (NANO-ADM). Over time, the ADM will offer its services and capabilities in medical countermeasures to broader customer bases, including the U.S. Department of Health and Human Services, as well as industry. NANO-ADM will provide flexible, single-use, disposable equipment that will fit national security requirements for the Medical Counter Measures program.

2013



Thermo Fisher Scientific Joins Momentum Labs as Founding Sponsor of New Biotech Hub in Alachua

https://gainesvillebizreport.com/nanotherapeutics-breaks-ground-on-new-facility-in-alachua/

Statement of

Bryce H. P. Mendez
Specialist in Defense Health Care Policy

Before

Committee on Armed Services
Subcommittee on Personnel
U.S. Senate

Hearing on

"Department of Defense's efforts to ensure servicemembers' access to safe, high-quality pharmaceuticals"

April 30, 2024

Congressional Research Service
https://crsreports.congress.gov
TE10099

2013

Congressional Research Service
Informing the legislative debate since 1914

TESTIMONY

DOD Advanced Development and Manufacturing Biopharmaceutical Facility

The Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), an office under the Chemical and Biological Defense Program, administers the DOD Advanced Development and Manufacturing (ADM) Biopharmaceutical Facility located in Alachua, FL.[31] The ADM facility is a contractor-owned, contractor-operated facility that provides DOD with an "enduring capability and infrastructure" to meet military medical requirements and the "capability for agile and flexible advanced development and manufacturing" of medical countermeasures.[32] In December 2010, then-Assistant to the President for Homeland Security, John O. Brennan, transmitted a memorandum calling for the Secretary of Defense to "establish agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of medical countermeasures."[33] In response to this directive, on March 21, 2013, Army Contracting Command awarded a $135.8 million contract to then-Nanotherapeutics Inc. to build and operate the ADM facility, which provides DOD with "priority access" to the contractor's manufacturing capabilities in order to "produce medical countermeasures more quickly and more effectively than other drug makers."[34] According to JPEO-CBRND, the ADM facility is compliant with cGMP regulations, certified for biosafety level-3 (BSL-3) research, and has developed biologics to address COVID-19, Botulism neurotoxin, and other health threats.[35]

https://crsreports.congress.gov/product/pdf/TE/TE10099

Response: A series of Policies track after Events

POLICY

- Bioterrorism Act (2001)
- Project BioShield (2003)
- ASPR Pandemic & All Hazards Preparedness Act (2005)
- National Health Security Strategy (2009)
- MCM Enterprise Review (2010)
- PHEMCE Strategy & Implementation Plan (2012)
- PAHPA Reauthorized (2013)

2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

EVENTS

- 9/11 and Anthrax (2001)
- Re-emerging H5N1 (2003)
- Katrina, Rita, Wilma (2005)
- Ike, Gustav (2008)
- H1N1 Pandemic (2009)
- Haiti earthquake (2010)
- Deepwater Horizon and Tornadoes (2011)
- Japan Earthquake Nuclear Event (2012)
- Hurricanes Isaac and Sandy (2013)
- Boston bombings (2014)
- Ebola MERS Chikungunya (2015)
- Zika (2016)

ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

DC, July 25, 2017, at https://www.ausa.org/sites/default/files/army-medical-eckels.pdf; and WRAIR, "Pilot Bioproduction Facility (PBF)," fact sheet, November 2022, at https://wrair.health.mil/Portals/87/Documents/PBF%20Handout%202022_Updated_21NOV22_final.pdf.

[29] Ibid; and WRAIR briefing and discussions with CRS, October 2023.

[30] Ibid.

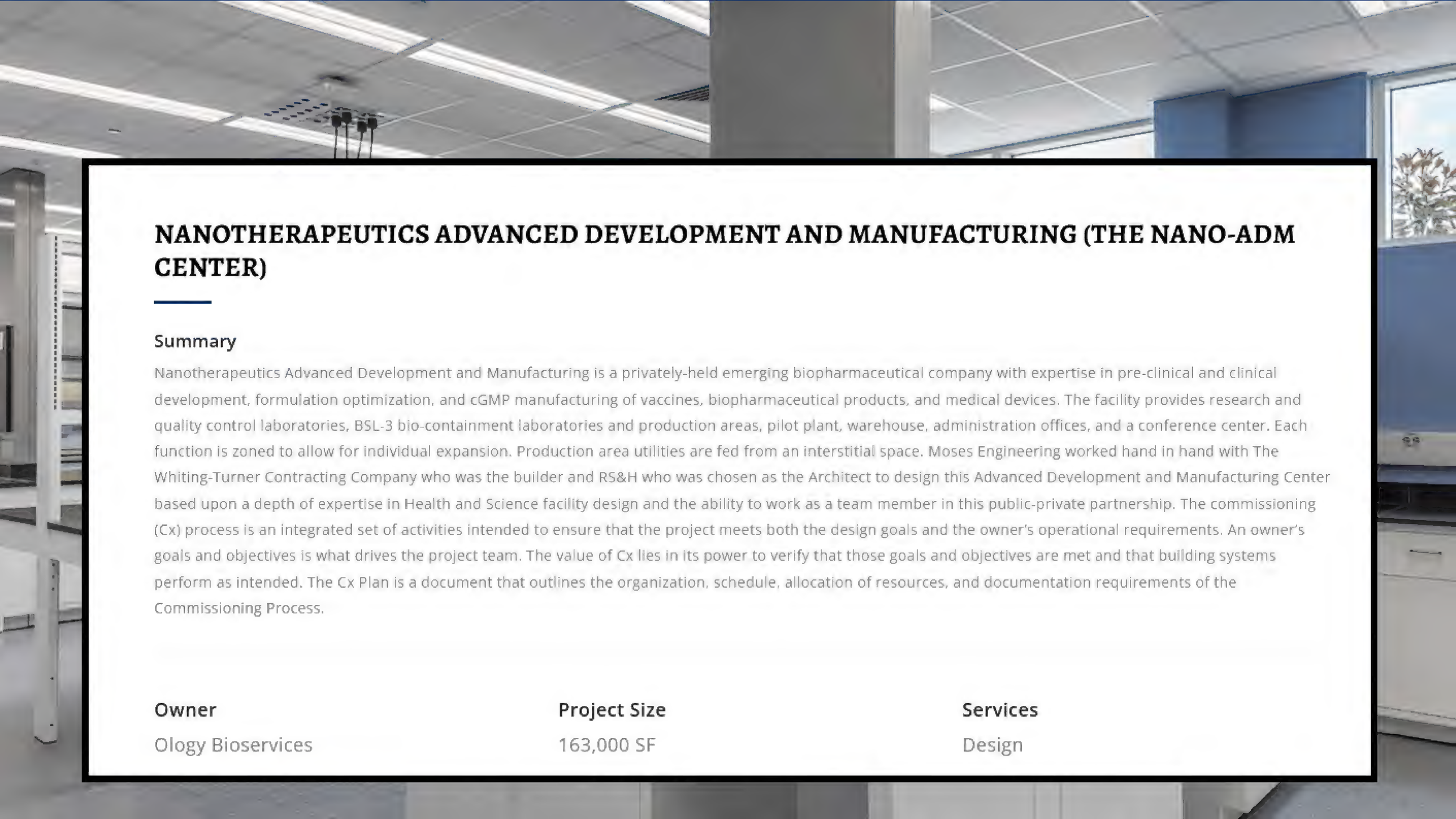
[31] Kelly Burkhalter and Chris Southworth, "Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience," *JPEO-CBRND News*, December 5, 2023, at https://www.jpeocbrnd.osd.mil/Media/News/Article/3607443/enduring-capability-jpeo-cbrnd-evolves-publicprivate-partnership-with-national/#:~:text=Located%20in%20Alachua%2C%20Florida%2C%20the,agents%20and%20emerging%20infectious%20 diseases.

[32] SAM.gov, "A—Medical Countermeasure Manufacturing Advanced Development Manufacturing (ADM) Capability," Presolicitation Notice ID W911QY11R0023, August 9, 2011, at https://sam.gov/opp/6d98c844d9d76510d7cf6bfdeffcf33e/view.

[33] U.S. Government Accountability Office (GAO), *Biological Defense: Additional information that Congress may find useful as it considered DOD's advanced development and manufacturing capability*, GAO-17-701, July 2017, p. 7, at https://www.gao.gov/assets/gao-17-701.pdf; and White House, Memorandum for the Secretary of Defense, "Medical Countermeasures against Biological and Other Public Health Threats," December 29, 2010.

[34] DOD, "Contracts for March 21, 2013," accessed April 8, 2024, at https://web.archive.org/web/20130408205027/http://www.defense.gov/contracts/contract.aspx?contractid=5002; Kelly Burkhalter, "Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience," *JPEO-CBRND News*, December 4, 2023, at https://www.dvidshub.net/news/459375/enduring-capability-jpeo-cbrnd-evolves-public-private-partnership-with-national-resilience; and Anthony Clark, "U.S. Department of Defense Expands Medical Countermeasure Capabilities," *JPEO-CBRND News*, December 20, 2016, at https://www.jpeocbrnd.osd.mil/Media/News/Article/2597346/us-department-of-defense-expands-medical-countermeasure-capabilities/. In 2017, Nanotherapeutics, Inc. was renamed to Ology Bioservices, Inc. In 2021, National Resilience, Inc. acquired Ology Bioservices.

[35] Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), "Medical Countermeasures Advanced Development and Manufacturing (ADM), accessed April 8, 2024, at https://www.jpeocbrnd.osd.mil/Portals/90/fact-sheet_adm.pdf; JPEO-CBRND, "JPEO-CBRND Capabilities Catalog," 2023, at https://www.jpeocbrnd.osd.mil/Portals/90/Documents/JPEO-CBRND_Capabilities%20Catalog_20%20April%202023_Final.pdf; and Hannah Feldman, Chris Earhart, and Traci Pals, "Toxic at Best," *JPEO-CBRND News*, January 22, 2019, at https://www.jpeocbrnd.osd.mil/Media/News/Article/2593990/toxic-at-best/.



NANOTHERAPEUTICS ADVANCED DEVELOPMENT AND MANUFACTURING (THE NANO-ADM CENTER)

Summary

Nanotherapeutics Advanced Development and Manufacturing is a privately-held emerging biopharmaceutical company with expertise in pre-clinical and clinical development, formulation optimization, and cGMP manufacturing of vaccines, biopharmaceutical products, and medical devices. The facility provides research and quality control laboratories, BSL-3 bio-containment laboratories and production areas, pilot plant, warehouse, administration offices, and a conference center. Each function is zoned to allow for individual expansion. Production area utilities are fed from an interstitial space. Moses Engineering worked hand in hand with The Whiting-Turner Contracting Company who was the builder and RS&H who was chosen as the Architect to design this Advanced Development and Manufacturing Center based upon a depth of expertise in Health and Science facility design and the ability to work as a team member in this public-private partnership. The commissioning (Cx) process is an integrated set of activities intended to ensure that the project meets both the design goals and the owner's operational requirements. An owner's goals and objectives is what drives the project team. The value of Cx lies in its power to verify that those goals and objectives are met and that building systems perform as intended. The Cx Plan is a document that outlines the organization, schedule, allocation of resources, and documentation requirements of the Commissioning Process.

Owner

Ology Bioservices

Project Size

163,000 SF

Services

Design

Department of Defense
Fiscal Year (FY) 2020 Budget Estimates

March 2019

Chemical and Biological Defense Program

Defense-Wide Justification Book Volume 4 of 5

Research, Development, Test & Evaluation, Defense-Wide

https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2020/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB20_Justification_Book.pdf

Chemical &

Defense-W

ch, Develop

Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		**Date:** March 2019
Appropriation/Budget Activity 0400 / 4	**R-1 Program Element (Number/Name)** PE 0603884BP / *CHEMICAL/BIOLOGICAL DEFENSE (ACD&P)*	**Project (Number/Name)** MB4 / *MEDICAL BIOLOGICAL DEFENSE (ACD&P)*

emerging threats. Once established, future programs will be able to leverage these platforms for the development of future medical countermeasures. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.

ADVANCED DEVELOPMENT & MANUFACTURING (ADM)

A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) ADM Facility to rapidly develop, approve (through FDA approval), and manufacture MCMs. The contract was structured to be executed in two (2) phases:

Phase 1-Establish, commission and validate (facility(ies)/ equipment) for two (2) advanced development and manufacturing suites that use agile, flexible (single use, disposable), modular and multi-product technologies for MCM advanced development and manufacturing. Both suites must meet Biological Safety Level-3 (BSL-3) standards. Phase 1 was completed on 31 March 2017.

Phase 2-Support and maintain that capability in a state of readiness to support MCM development (under the animal rule as applicable) and manufacturing and assist in training personnel in its use. This includes transition and integration of new technologies, from Pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure. The first option is scheduled for completion in 2QFY19, proceeded by a second, 2-year option.

BSL4 GOOD LABORATORY PRACTICES TEST & EVALUATION (BSL4 GLP T&E)

The Medical Countermeasure Systems (MCM) BSL-4 T&E capability continues to utilize and maintain a testing capability at the existing and planned new USAMRIID facilities. MCM BSL-4 T&E costs support testing of MCMs against threats that require high-level containment using non-human primates. The period of FY18 and beyond will continue to support the BSL-4 T&E capability.

COUNTERMEASURES FOR DRUG RESISTANT BACTERIA (CMDR-B)

The CMDR-B program develops MCMs for Service members for protection against MDR bacteria, including Biological Warfare Agents (BWAs) and organisms that are genetically modified to be MDR and resulting bio-toxins. The resulting product(s) will be US Food and Drug Administration (FDA)-approved to prevent or minimize effects of MDR bacterial exposures. The candidate is a transitional product from S&T that showed efficacy against plague, anthrax, and other BW agents. The regulatory approach of the program is to pursue development of products to FDA approval under the Animal Rule. The program will conduct non-human primate studies to initial efficacy. The performer will submit Supplemental New Drug Application for the therapeutic during the EMD Phase. In FY18 PK study on non-human primates was completed for the plague indication. MS B for the program is planned for 4QFY20.

NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)

The NGDS Increment 1 program was a MS A to MS C - acquisition strategy, with MS C approval granted in Dec 2016 for limited production and fielding. NGDS 1 is replacing the legacy Joint Biological Agent Identification and Diagnostic System (JBAIDS) beginning in FY17. NGDS 1 Full Rate Production was approved in Aug 2018.

Department of Defense
Fiscal Year (FY) 2020 Budget Estimates
March 2019

Chemical and Biological Defense Program
Defense-Wide Justification Book Volume 4 of 5
Research, Development, Test & Evaluation, Defense-Wide

Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		**Date:** March 2019
Appropriation/Budget Activity 0400 / 5	**R-1 Program Element (Number/Name)** PE 0604384BP / *CHEMICAL/BIOLOGICAL DEFENSE (EMD)*	**Project (Number/Name)** MB5 / *MEDICAL BIOLOGICAL DEFENSE (EMD)*

JOINT MOBILE EMERGING DISEASE INTERVENTION CLINICAL CAPABILITY (JMEDICC)

The Joint Mobile Emerging Disease Intervention Clinical Capability (JMEDICC) is a collaboration between United States and Ugandan research and outbreak response entities. It currently is a joint effort with The United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and The Naval Medical Research Center (NMRC) to enable clinical trials for filovirus (i.e., Ebola and Marburg) therapeutics during an outbreak. Prior to Fiscal Year 2020, this effort was funded under the Antiviral Therapeutics (AV TX) Program. The JMEDICC effort is currently focused on filovirus, but is an adaptable capability that can incorporate multiple different medical countermeasures (MCM) in parallel and accommodate multiple site activities. This will maximize JMEDICC's current response capability and infrastructure by expanding as the endemic situation warrants. A cost sharing plan is currently being explored with other government and nongovernment agencies to determine interest and relevance levels. Antiviral Therapeutics program funded JMEDICC effort through FY19.

ADVANCED DEVELOPMENT & MANUFACTURING (ADM)

A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) ADM Facility to rapidly develop, approve (through FDA approval), and manufacture MCMs. The contract was structured to be executed in two (2) phases:

Phase 1-Establish, commission and validate (facility(ies)/ equipment) for two (2) advanced development and manufacturing suites that use agile, flexible (single use, disposable), modular and multi-product technologies for MCM advanced development and manufacturing. Both suites must meet Biological Safety Level-3 (BSL-3) standards. Phase 1 was completed on 31 March 2017.

Phase 2-Support and maintain that capability in a state of readiness to support MCM development (under the animal rule as applicable) and manufacturing and assist in training personnel in its use. This includes transition and integration of new technologies, from Pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure. The first option is scheduled for completion in 2QFY19, proceeded by a second, 2-year option.

COUNTERMEASURES FOR DRUG RESISTANT BACTERIA (CMDR-B)

The CMDR-B program develops MCMs for Service members for protection against MDR bacteria, including Biological Warfare Agents (BWAs) and organisms that are genetically modified to be MDR and resulting bio-toxins. The resulting product(s) will be US Food and Drug Administration (FDA)-approved to prevent or minimize effects of MDR bacterial exposures. The candidate is a transitional product from S&T that showed efficacy against plague, anthrax, and other BW agents. The regulatory approach of the program is to pursue development of products to FDA approval under the Animal Rule. The program will conduct non-human primate studies to initial efficacy. The performer will submit Supplemental New Drug Application for the therapeutic during the EMD Phase. In FY18 PK study on non-human primates was completed for the plague indication. MS B for the program is planned for 4QFY20.

NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)

February 2020

Exhibit R-2A, RDT&E Project Justification: PB 2021 Chemical and Biological Defense Program		Date: February 2020
Appropriation/Budget Activity 0400 / 4	**R-1 Program Element (Number/Name)** PE 0603884BP / *CHEMICAL/BIOLOGICAL DEFENSE (ACD&P)*	**Project (Number/Name)** MB4 / *Medical Biological Defense (ACD&P)*

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
• JX0210: *DEFENSE BIOLOGICAL PRODUCTS ASSURANCE PROGRAM (DBPAP)*	0.975	2.961	2.845	-	2.845	2.760	2.736	2.736	2.736	Continuing	Continuing

Remarks

D. Acquisition Strategy

BSL4 GOOD LABORATORY PRACTICES TEST & EVALUATION (BSL4 GLP T&E)

The Medical Countermeasure Systems (MCM) BSL-4 T&E capability continues to utilize and maintain a testing capability at the existing and planned new USAMRIID facilities. MCM BSL-4 T&E costs support testing of MCMs against threats that require high-level containment using non-human primates. The period of FY18 and beyond will continue to support the BSL-4 T&E capability. In FY21 and beyond, the Defense-Wide Review reduced this program for higher priorities.

CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - BIOSAFETY LEVEL 4 RESEARCH INSTITUTE OF INFECTIOUS DISEASES (CBIPR-BSL4 RIID)

The Medical Countermeasure Systems (MCM) BSL-4 T&E capability continues to utilize and maintain a testing capability at the existing and planned new USAMRIID facilities. MCM BSL-4 T&E costs support testing of MCMs against threats that require high-level containment using non-human primates. The period of FY18 and beyond will continue to support the BSL-4 T&E capability.

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Chemical and Biological Defense Program

https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2021/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB21_Justification_Book.pdf

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Chemical and Biological Defense Program

February 2020

Exhibit R-2A, RDT&E Project Justification: PB 2021 Chemical and Biological Defense Program		Date: February 2020
Appropriation/Budget Activity 0400 / 5	**R-1 Program Element (Number/Name)** PE 0604384BP / *CHEMICAL/BIOLOGICAL DEFENSE (EMD)*	**Project (Number/Name)** MB5 / *Medical Biological Defense (SDD)*

CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - ADM

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MCM PLATFORM TECHNOLOGIES (MCMPT)

The goal of the MCMPT is to rapidly counter a broad-spectrum of threat agents using standardized discovery, design, manufacturing, and testing processes to reduce the MCM development risks. Efforts will focus on establishing advanced platform technologies within the DoD's Advanced Development Manufacturing (ADM) facility and evaluating that capability through nonclinical and clinical testing. A subset of these technologies will be adapted to deliver a rapid response capability to novel and emerging threats. Once established, future programs will be able to leverage these platforms for the development of future medical countermeasures. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.

NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)

https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2021/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB21_Justification_Book.pdf

May 2021

Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 5	**R-1 Program Element (Number/Name)** PE 0604384BP / *CHEMICAL/BIOLOGICAL DEFENSE (EMD)*	**Project (Number/Name)** MB5 / *Medical Biological Defense (SDD)*

The COVID TX program will conduct Phase 2 clinical trials in FY20 and FY21 to test the efficacy of the Leukine (sargramostim, rhu-GM-CSF) in COVID-19 patients with acute hypoxemia to inform a request for Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA). Qualification of a second manufacturing line for Drug Product Agreement awarded to performer for clinical trials, submission of EUA, and manufacturing expansion.

ANTI-VIRAL THERAPEUTICS (AV TX)

The Anti-viral Therapeutics (AVTX) program acquisition strategy supports the development of therapeutics through the Engineering, Manufacturing and Development (EMD) phase against the Ebola (Zaire), Marburg and Sudan bio warfare threats. The initial therapeutic candidate is now for a treatment against the Marburg virus in lieu of Ebola Zaire based on the current gap in defense to the warfighter. The overall regulatory approach of the program remains to pursue development of products to Food and Drug Administration (FDA) approval under the Animal Rule that was approved as the path, by the FDA in 1QFY19. The program completed a dose ranging study for the Ebola Zaire indication and initiated a Natural History Study for Marburg that is part of the holistic FDA regulatory approach for a final indication of a broad spectrum antiviral pan filo drug product. A natural history study for Marburg and Sudan and 3 pivotal animal studies per indication are required as part of the animal rule requirements for the FDA) approved plan. The acquisition strategy for Marburg and Sudan indications will have the performer submitting amended New Drug applications for the therapeutics during the EMD phase.

BOTULINUM MONOCLONAL ANTIBODIES (BOT MAB)

Initiated by the Medical Countermeasure Platform Technologies (MCMPT), the goal of Botulinum Monoclonal Antibodies (BOT MAB) advanced development effort is to counter exposure to BOT A & B toxins. The program is leveraging the advanced platform technology developed within the DoD's Advanced Development Manufacturing (ADM) facility that was initiated by the Medical Countermeasure Platform Technologies (MCMPT). The BOT MAB will be a monoclonal antibody cocktail that protects the warfighter against exposure to BOT A&B serotypes.

COUNTERING EMERGING THREATS RAPID ACQUISITION AND INVESTIGATION OF DRUGS FOR REPURPOSING (CET RAIDR)

The Countering Emerging Threats - Rapid Acquisition and Investigation of Drugs for Repurposing (CET RAIDR) program will leverage lessons learned from the COVID-19 response to conduct nonclinical studies and Phase 2 and 3 trials in support of requesting pre-Emergency Use Authorizations (pre-EUA). Repurposing reports will be issued to Combatant Commands to inform clinical practitioners, and Food and Drug Administration (FDA) approvals for those efforts initiated under the Coronavirus Disease Repurposed Therapeutics (COVID TX) program, as well as products that transition from Science and Technology (S&T) efforts for new and emerging threats.

CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - ADM

A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) Advanced Development and Manufacturing (ADM) capability that can rapidly develop and manufacture MCMs from early stage development up through FDA licensure. The establishment of this capability consisted of designing, commissioning, and validating a biopharmaceutical facility (both its infrastructure and equipment) that is equipped with two (2)

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https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2022/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB22_Justification_Book.pdf

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
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A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) Advanced Development and Manufacturing (ADM) capability that can rapidly develop and manufacture MCMs from early stage development up through FDA licensure. The establishment of this capability consisted of designing, commissioning, and validating a biopharmaceutical facility (both its infrastructure and equipment) that is equipped with two (2) advanced development and manufacturing suites, which utilize flexible, agile, single-use (disposable), modular, and multi-product technologies that comply with GMPs and can operate at Biological Safety Level-3 (BSL-3). The capability was established on 31 March 2017.

Since its establishment, the DoD ADM has been sustained in a state of operational readiness so that it can continue to be an enduring domestic MCM manufacturing capability that provides the DoD with priority access. The original sustainment strategy consisted of directly funding all costs/activities (i.e. calibration, maintenance, etc.) via sustainment options on the original contract. The CBIPR funds were designated to support this critical DoD infrastructure. The CBIPR-ADM funding line supports the infrastructure by funding new capability-building efforts (such as manufacturing platforms using FDA known technologies) that will enable new additional MCM product development. This strategy will result in the self-sustainability of the DoD ADM by spreading the sustainment costs equally across all projects (including commercial clients), which mimics the standard practice across the contract development and manufacturing organization (CDMO) industry.

MCM PLATFORM TECHNOLOGIES (MCMPT)

The goal of the MCMPT is to rapidly counter a broad-spectrum of threat agents using standardized discovery, design, manufacturing, and testing processes to reduce the MCM development risks. Efforts will focus on establishing advanced platform technologies within the DoD's Advanced Development Manufacturing (ADM) facility and evaluating that capability through nonclinical and clinical testing. A subset of these technologies will be adapted to deliver a rapid response capability to novel and emerging threats. Once established, future programs will be able to leverage these platforms for the development of future medical countermeasures. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.

NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)

The NGDS 1 program was a MS A to MS C - acquisition strategy, with MS C approval granted in Dec 2016. NGDS 1 replaces the legacy Joint Biological Agent Identification and Diagnostic System (JBAIDS). NGDS 1 Full Rate Production was approved in Aug 2018.

NGDS 2 will employ a family of systems approach to bridge identified capability gaps for man-portable diagnostics, immunoassay diagnostics, and chemical diagnostics systems. NGDS 2 continued the technology maturation and risk reduction of a man-portable diagnostic capability in FY18 and transitioned to engineering and manufacturing development phase in FY19. NGDS 2 initiated prototyping of a chemical diagnostic capability in FY18. Separate decisions will be utilized to proceed with further development and production for each capability, based on individual determinations of technology maturity to meet user requirements. Development efforts are cost-plus awards using Other Transactions Authority (OTA) agreements to take advantage of nontraditional Defense contractor offerings. NGDS 2 will transition into NGDS 2 CHEMDx and NGDS 2 MPDS starting in FY21.

NEXT GEN DIAG 2 CHEMICAL DIAGNOSTICS (NGDS 2 CHEMDX)

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OPERATIONS

Strategic Alliance Formed To Advance National Biodefense Programs

PharmAthene and Nanotherapeutics, a privately-held biopharmaceutical company, have announced that they have formed a Strategic Alliance to advance the development of certain medical countermeasures for the U.S. biodefense market. Under the Alliance Agreement, each company will contribute...

By The Associated Press

Sep 8, 2014

PharmAthene, Inc. and Nanotherapeutics, Inc., a privately-held biopharmaceutical company, have announced that they have formed a Strategic Alliance to advance the development of certain medical countermeasures for the U.S. biodefense market. Under the Alliance Agreement, each company will contribute its specific expertise and resources with the objective of advancing biodefense products to be agreed to under individual product plans.

Latest in Operations

Chemovator Invests in Detroit-Based Startup, Rethinking Plastics

May 2, 2024

https://www.manufacturing.net/operations/news/13095313/strategic-alliance-formed-to-advance-national-biodefense-programs

ADEPT : PROTECT

DARPA P3

THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses

THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats

Gene-encoded antibodies
for near-immediate, temporary protection
(ADEPT-PROTECT)

Proof of concept in animal models (6.1)
2013-2016

Pre-clinical studies & GMP manufacture (6.1 to 6.2)
2017-2018

Gene-encoded antibody safety and expression study in humans (performer funded)
2018-2020

PANDEMIC PREVENTION PLATFORM (P3)

60 DAYS TO STOP A PANDEMIC

A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.

https://www.darpa.mil/attachments/ADEPTVignetteFINAL.pdf

ADEPT : PROTECT

THE NEED AND OPPORTUNITY

A primary objective of DARPA's Biological Technologies Office (BTO) is to better ensure the health, and thereby the force readiness, of the country's military service community. The COVID-19 pandemic, which rapidly spread worldwide from an initial outbreak in China at the end of 2019, highlights one of the most perilous vulnerabilities to deployed military personnel and civilians: lack of protection and medical countermeasures (MCMs) against endemic and emerging biothreats. The Zika outbreak in 2015-2016, the more recent Ebola outbreak in the Democratic Republic of Congo, and mosquito-borne viruses such as Chikungunya and Dengue are among these threats.

Vaccines are the traditional mainstay of long-term infection prevention, while antibody approaches have at times been used to treat active infections. In one antibody-based approach that is being applied on a small scale in the current pandemic, blood serum with presumably protective antibodies obtained from those who have recovered from an infection is infused into patients. In more recent decades, monoclonal antibodies manufactured in cultured immune-system cells have been used to treat certain cancers and immune disorders. However, these treatments have suffered from shortcomings – including slow development, expensive manufacture, and dependence on continuous cold storage – that have prevented widespread use by the military.

THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses like the one (SARS-CoV-2) that causes COVID-19, are delivered directly to a recipient's body. There, the instructions carried in the DNA or RNA elicit the body's own cells to manufacture the antigenic viral protein, which, in turn, elicits an immune response to the virus.

A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.

Gene-based vaccines have shown great promise as a means to provide safe, reproducible, long-term immune protection. For vaccines to work, however, they often require more than one dose and it often takes weeks to months before a recipient's immune system builds up sufficient protection again the vaccine's viral target. With these biomedical realities come threats to warfighters if they deploy to pathogen-rife regions before having established relevant immunity and threats to military missions due to delayed deployment of personnel until they achieve immune protection.

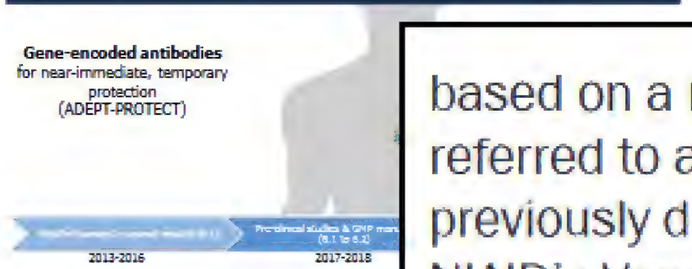
For a vaccine to confer immunity, it must lead to the production within a recipient of highly potent antibodies that can neutralize the pathogen. DARPA initiated the ADEPT:PROTECT program (most often referred to more simply as ADEPT) with the intention of bushwhacking a novel pathway to near-immediate protection against pathogens for which vaccines are not yet available and to confer interim-term protection during the development of a vaccine, which can take years.

THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

Earlier proof-of-concept experiments funded under ADEPT primarily with 6.1 funding (for basic research) demonstrated that delivery of antibody-making instructions — by way of messenger ribonucleic acid (mRNA), deoxyribonucleic acid (DNA), or another genetic-information-carrying tactic that relies on small viruses known as adenovirus-associated viruses (AAVs)

DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats



— led to the production of antibodies that conferred protection in test animals exposed to the mosquito-borne Chikungunya (ChikV) virus.

In a more applied phase of technology development, Moderna was converted to 6.2 funding (applied research) to begin pre-clinical studies in non-human primates with an RNA-encoded antibody against ChikV and to produce the countermeasure using Good Manufacturing Practices (GMP), which regulatory agencies such as the Food and Drug Administration often require.

Moderna subsequently used company funding to conduct a Phase I clinical trial with 22 healthy volunteers using an mRNA-encoded ChikV antibody. This marked the first safety demonstration of an RNA-based medical countermeasure. Moderna reported these promising results of its clinical study in 2019. The trial demonstrated platform safety as well as the ability to generate protective levels of functional antibody in humans. In response to COVID-19, Moderna in March 2020 initiated human trials of gene-encoded antibodies that target SARS-CoV-2.

Research by Moderna and other ADEPT performers has provided proof-of-concept results that simultaneously delivering gene-encoded antibody treatment and vaccine confers the recipient with immediate immune

based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017

based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017 Ebola outbreak in the Democratic Republic of Congo, where it conferred significant survival benefits over other EUA-sanctioned Ebola therapeutics. To enable continued availability of mAb-114, DARPA and JPEO-CBRND in 2018 co-funded the manufacture of additional doses at Ology Biosciences through its DoD-funded Advanced Development and Manufacturing (ADM) facility.

and Contagious Threats (ADEPT: PROTECT)

GEORGETOWN UNIVERSITY Georgetown University Medical Center

CENTER for GLOBAL HEALTH SCIENCE & SECURITY

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Col. Matthew Hepburn, M.D.

Center Affiliate

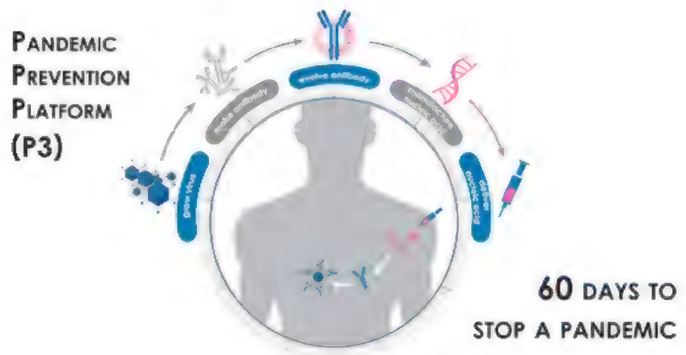
Col. Matthew Hepburn, M.D., is currently assigned to DARPA as a program manager, since 2013. Prior to joining DARPA, Col. Hepburn served as the Director of Medical Preparedness on the White House National Security Staff. Additional previous assignments include: Chief Medical Officer at a Level II medical facility in Iraq, clinical research director at the US Army Medical Research Institute for Infectious Diseases, exchange officer to the United Kingdom and internal medicine chief of residents at Brooke Army Medical Center at Fort Sam Houston, Texas.

Col. Hepburn completed internal medicine residency and infectious diseases fellowship programs at Brooke Army Medical Center. He holds Doctor of Medicine and Bachelor of Science in biomedical engineering degrees from Duke University.

Removing the Viral Threat: Two Months to Stop Pandemic X from Taking Hold

DARPA aims to develop an integrated end-to-end platform that uses nucleic acid sequences to halt the spread of viral infections in sixty days or less

OUTREACH@DARPA.MIL
2/6/2017



Over the past several years, DARPA-funded researchers have pioneered RNA vaccine technology, a medical countermeasure against infectious diseases that uses coded genetic constructs to stimulate production of viral proteins in the body, which in turn can trigger a protective antibody response. As a follow-on effort, DARPA funded research into genetic constructs that can directly stimulate production of antibodies in the body.[1,2] DARPA is now launching the Pandemic Prevention Platform (P3) program, aimed at developing that foundational work into an entire system capable of halting the spread of any viral disease outbreak before it can escalate to pandemic status. Such a capability would offer a stark contrast to the state of the art for developing and deploying traditional vaccines —a process that does not deliver treatments to patients until months, years, or even decades after a viral threat emerges.

"DARPA's goal is to create a technology platform that can place a protective treatment into health providers' hands within 60 days of a pathogen being identified, and have that treatment induce protection in patients within three days of administration. We need to be able to move at this speed considering how quickly outbreaks can get out of control," said Matt Hepburn, the P3 Program Manager. "The technology needs to work on any viral disease, whether it's one humans have faced before or not."

Revista de la Escuela Jacobea de Posgrado *http://revista.jacobea.edu.mx/*
Nº 24, junio 2023, págs. 1-16 *ISSN 2007-3798*

PUBLIC PROCUREMENT AND DISRUPTIVE TECHNOLOGIES: DARPA'S ROLE IN THE DEVELOPMENT OF mRNA VACCINES[1]

Contratación pública y tecnologías disruptivas: el papel de DARPA en el desarrollo de vacunas de ARNm

BY: PHD. LIEUTENANT COLONEL DANIEL SCHOENI, USAF[2]
Judge Advocate at U.S Air Force Materiel Command, Dayton, Ohio
dschoeni@law.gwu.edu

RESUMEN: Uno de los propósitos clave del Departamento de Defens
Unidos (DoD) es proporcionar capacidades para ganar la guerra a solc
infantes de marina, aviadores y guardianes. Debido a la naturaleza única
de defensa, esto requiere una constante innovación. Desde la década de
tecnología militar se volvió demasiado sofisticada para los arsenales gu
DoD ha confiado principalmente en contratistas del sector pr
especializados. Sin embargo, para ciertas inversiones en ciencia básic
fallas del mercado, el DoD destina recursos a sus propios esfuerzos d
desarrollo. La institución gubernamental más famosa de estas es la Age
de Investigación Avanzada de Defensa (DARPA), cuyas invencior
aviones furtivos, sistemas de posicionamiento global e internet. Sin
ocurre en la mayoría de los países, una gran parte de la innovación se q
privado. Este artículo explora lo que hace excepcional a DARPA, exar
en el desarrollo de tecnologías de ARNm utilizadas posteriormente
vacunas contra el COVID-19. Y advierte que DARPA puede no ser esc

PALABRAS CLAVE: DARPA; tecnologías disruptivas; contratación
mRNA.

ABSTRACT: One of the key purposes of the U.S. Department of Def
deliver war-winning capabilities to soldiers, sailors, marines, airmer
Because of the unique nature of defense procurement, this requires cor
Since the 1950s, when military technology became too sophisticated
arsenals, the DoD has primarily relied on highly specialized defense
private sector. However, for certain investments in basic science or to c
failures, the DoD devotes resources to its own research and developm
most famous of these government institutions is the Defense Advanced
Agency (DARPA), whose inventions have included stealth aircraft, g

[1] * Recibido para publicación: 8 de enero 2023
Aceptado para publicación: 17 de marzo 2023
[2] The opinions expressed here are those of the author and do not necessarily reflect
position of the Department of the Air Force, the Department of Defense, or any other U.S. government
agency. This was article was first presented at a virtual conference sponsored by the University of Vigo on
4 October 2021, Temas clave de la contratación pública. The author is grateful to Major Ashley Ruhe,
USAF, and to Professor Patricia Valcárcel Fernández, University of Vigo, for valuable contributions

DARPA's Role in the Development of mRNA Vaccines

Revista de la Escuela Jacobea de Posgrado, Nº 24, junio 2023, págs. 1-16

16 Pages • Posted: 5 Jul 2023 • Last revised: 17 Jul 2023

Daniel Schoeni
U.S. Air Force JAG Corps

Date Written: June 26, 2023

Abstract

One of the key purposes of the U.S. Department of Defense (DoD) is to deliver war-winning capabilities to soldiers, sailors, marines, airmen, and guardians. Because of the unique nature of defense procurement, this requires constant innovation. Since the 1950s, when military technology became too sophisticated for government arsenals, the DoD has primarily relied on highly specialized defense contractors in the private sector. However, for certain investments in basic science or to circumvent market failures, the DoD devotes resources to its own research and development efforts. The most famous of these government institutions is the Defense Advanced Research Projects Agency (DARPA), whose inventions have included stealth aircraft, global positioning systems, and the internet. Nevertheless, as in most countries, most innovation occurs in the private sector. This article explores what makes DARPA exceptional, examining its role in the development of mRNA technologies later used to develop COVID-19 vaccines. And it cautions that DARPA may not be scalable.

When Dan Wattendorf arrived at DARPA's biological technologies office in 2010, mRNA technology already existed. The possibility of using the body's own DNA for producing vaccines was recognized as early as 1950. In 2005, Katalin Karikó and Drew Weissman discovered a way to alter mRNA that would increase its therapeutic potential. Wattendorf sought to stimulate research into lipid-based mRNA delivery systems.[17] Even with financial support, large pharmaceutical companies still weren't interested. Wattendorf turned to newer biotech companies, and in 2013 DARPA issued a $25 million grant to a company, which is now a household name: Moderna.[18] As its name would imply (given that the last there letters spell out "RNA" in English), it concentrated on using mRNA to develop human vaccines.[19] By 2019, it had produced the first effective vaccine using mRNA technology.[20] Thus, the fact that DARPA had already made key investments in vaccines pre-COVID underlay the unbelievably rapid pace of OWS.[21]

Apart from its support of mRNA vaccine research a decade before the coronavirus struck, DARPA's organizational structure also served as a model for OWS.[23] OWS was launched on May 15, 2020, and this signaled a partnership between the Department of Health and Human Services, the DoD, and pharmaceutical companies.[24] Several key features of DARPA's structure were incorporated.

DARPA has been credited with several transformative technologies, including ARPANET (the internet), the engines that powered the Apollo missions, GPS, and flat panel displays.[25] One secret of its success lay in doing "connected science". Rather than conducting only basic research, DARPA prides itself in simultaneously mobilizing private-sector production, "enabling full innovation not simply invention."[26] This is a key feature of the DARPA model.

The DARPA model entails several other key elements. First, it is small, composed of only 50–100 program managers.[27] Second, unlike most military organizations, its structure eliminates the typical hierarchy and has only two levels, which fosters cooperation.[28] Third, its technical staff are employed by DARPA for at most 3–5 years, encouraging fresh thinking and reducing careerism.[29] Fourth, it uses a "portfolio approach", funding multiple lines of research in parallel, knowing many of these will surely fail.[30] Last, DARPA utilizes flexible contracting procedures, especially the renowned "Other Transactions Authority" (OTA).[31]

ABCELLERA

BILL & MELINDA GATES foundation

DARPA

AbCellera

Article Talk

From Wikipedia, the free encyclopedia

AbCellera Biologics Inc. is a Vancouver, British Columbia-based biotechnology firm that researches and develops human antibodies. The company is best known for its leading role in the Pandemic Prevention Platform, a project of DARPA's Biological Technologies Office.[1] AbCellera utilizes a proprietary technology platform, which they claim can develop "medical countermeasures within 60 days."[2] Its platform for single-cell screening was initially developed at the University of British Columbia.[3]

AbCellera Biologics Inc.

Company type	Public
Traded as	Nasdaq: ABCL
Industry	Biotechnology
Founded	2012; 12 years ago
Headquarters	Vancouver, British Columbia
Revenue	375.2 million (2021)
Number of employees	386 (2021)
Website	www.abcellera.com

History [edit]

AbCellera was founded in 2012 by biomedical researchers Carl Hansen, Véronique Lecault, Kevin Heyries, Daniel Da Costa and Oleh Petriv. In November 2016, the company received a US$645K grant from the Bill & Melinda Gates Foundation to develop a test for tuberculosis.[4] In September 2018, a $10M series A round of funding was closed.[5] In May 2020, a $105M series B round of funding was closed.[6][7]

In January 2017, AbCellera announced that it would be collaborating with Pfizer to discover and develop antibodies against membrane protein targets."[8][9]

Pfizer

ABCELLERA

Palantir

Lilly

COVID-19 and expansion [edit]

In June 2020, AbCellera announced it had begun the world's first study of a potential antibody treatment against COVID-19, with a Phase 1 trial of LY-CoV555 (Bamlanivimab), in collaboration with Eli Lilly and Company.[10] The drug was granted an Emergency Use Authorization by the U.S. Food and Drug Administration in November 2020, and subsequently renewed in February and March 2021.[11][12] The EUA was revoked in April 2021, with the FDA citing an updated conclusion that "the known and potential benefits of bamlanivimab alone no longer outweigh the known and potential risks for the product," because of significantly reduced efficacy against emerging variants of SARS-CoV-2.[13] In November 2020, Peter Thiel joined AbCellera's board of directors and disclosed a 5.3% stake in the company.[14][15]

In September 2021, the company announced a multi-year agreement with Moderna to develop mRNA-based antibody treatments against multiple diseases.[16]

In January 2022, the company received a $1.5 million grant from the Bill & Melinda Gates Foundation to identify monoclonal antibodies against respiratory syncytial virus (RSV).[17] A second COVID-19 monoclonal antibody therapy (Bebtelovimab) was given Emergency Use Authorization in February 2022, with the U.S. Government committing to a $720 million purchase of up to 600,000 doses.[18]

Other partnerships include collaborations with Ablynx, Gilead Sciences, GlaxoSmithKline, Merck, Novartis, Sanofi and Teva Pharmaceutical Industries.[19][20]

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ENDPOINTSNEWS CHANNELS WEBINARS BIOPHARMA JOBS MORE

Carl Hansen, AbCellera CEO

February 14, 2022 07:06 AM EST FDA+, Coronavirus

As Omicron rages, FDA clears Eli Lilly/ AbCellera's new antibody days after $720M supply deal

Amber Tong
Senior Editor

The FDA has authorized a new Covid-19 antibody from Eli Lilly and AbCellera, adding a much-needed weapon to the arsenal fighting against Omicron.

Just days ago, the two companies unveiled a $720 million deal to supply 600,000 doses of the drug, bebtelovimab, to the US government. It may now be prescribed, under emergency use authorization, to adults and teenagers 12 or older with positive SARS-CoV-2 tests who are either at high risk for progression to severe disease

Bebtelovimab

2022

Eli Lily + Abecellera

$720M dollar deal with the USG

2022

PR Newswire

Send a Release

INOVIO to Develop DNA-encoded Monoclonal Antibody (dMAb®) Candidates to Treat COVID-19 with Funding from the Defense Advanced Research Projects Agency (DARPA) and the Department of Defense's (DoD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)

- DARPA to fund innovative public-private partnership between INOVIO, The Wistar Institute, AstraZeneca, the University of Pennsylvania and Indiana University

- $37.6 million grant from DARPA will leverage AstraZeneca's monoclonal antibody and INOVIO's DNA-encoded monoclonal antibody (dMAb®) technologies in the fight against COVID-19

- COVID-19 dMAbs offer a cost-effective treatment option, are fast to administer to subjects, and can be quickly manufactured and scaled up compared to traditional recombinant monoclonal antibody-based therapies

- dMAbs do not require cold chain transport/storage, and the overall approach can be applied beyond COVID-19 for any pathogen or disease that can be treated by recombinant monoclonal antibody-based therapies

DARPA

PROTECTING THE JOINT FORCE

JPEO-CBRND

INOVIO

Penn

University of Pennsylvania

AstraZeneca

NEWS PROVIDED BY

INOVIO Pharmaceuticals, Inc. →

Dec 15, 2020, 08:00 ET

mhttps://www.prnewswire.com/news-releases/inovio-to-develop-dna-encoded-monoclonal-antibody-dmab-candidates-to-treat-covid-19-with-funding-from-the-defense-advanced-research-projects-agency-darpa-and-the-department-of-defenses-dod-joint-program-executive-office-fo-301192706.html

LEADERSHIP

With a focus on operational excellence and financial discipline, our dedicated team has extensive experience bringing products to market to benefit patients.

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Emeritus Professor, Wistar Institute
and University of Pennsylvania;
Principal, Vaxconsult

David B. Weiner, Ph.D.
Executive Vice President, Director,
Vaccine Center, The Wistar Institute

Rafi Ahmed, Ph.D.

Director, Emory Vaccine Center, Emory University School of Medicine

Dr. Rafi Ahmed is the Georgia Research Alliance Professor of Microbiology and Immunology, and Director of the Emory Vaccine Center at Emory University Schoc of Medicine in Atlanta, GA. His research efforts are directed towards: 1. Understanding the mechanisms of immunological memory and using this knowledge to develop new and more effective vaccines. 2. Defining the mechanisms of T cell exhaustion during chronic viral infections and cancer and developing strategies for restoring function in exhausted T cells. Dr. Ahmed is a member of the National Academy of Sciences and the National Academy of Medicine.

Jacqueline Shea, Ph.D.

President & Chief Executive Officer

Dr. Shea has more than 25 years of experience in the life sciences and biotech industries. Prior to joining INOVIO, she was the CEO at Aeras, a not-for-profit organization dedicated to developing new vaccines against tuberculosis (TB). Previously, she held executive roles at Emergent BioSolutions and was also the General Manager and Vice President of The Oxford-Emergent Tuberculosis Consortium.

On INOVIO's board is the infamous Stanley Plotkin, as well as Rafi Ahmed from Emory. President of Inovio is Jacqueline Shea a former Emergent BioSolutions executive & VP of the Oxford-Emergent Tuberculosis Consortium.

https://inovio.com/about-inovio/leadership/

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Senior Vice President, Early-Stage Clinical Development

Dave Liebowitz, M.D. & Ph.D.

Senior Vice President, Early-Stage Clinical Development

Dr. Dave Liebowitz has over 27 years of industry experience in clinical and preclinical development in Oncology, Infectious Diseases (Virology), Vascular Biology, Inflammation and Metabolic Disorders with protein, small molecule, cellular therapeutic, and vaccine modalities. He was previously Senior Vice President, Clinical Development – Infectious Diseases at INOVIO. Prior to returning, Dr. Liebowitz was Senior Vice President, Clinical Development and Medical Affairs at Xencor, leading several immune-oncology programs. Prior to that, Dr. Liebowitz held numerous senior positions, including Chief Medical Officer at DNAtrix, an oncolytic virotherapy company in San Diego, CA; Chief Medical Officer at Vaxart, Inc. and Chief Scientific and Medical Officer for Vivaldi Biosciences, an influenza vaccine and therapeutics biotechnology company.

During his time at Vaxart, Inc., he led the successful application and negotiation process for acquiring a BARDA contract and served as the Principal Investigator of the award, leading its completion. In addition, he was an early recipient of a grant from the Bill and Melinda Gates Foundation.

Dr. Liebowitz began his academic career as an Assistant Professor of Medicine and Virology at the University of Chicago and was the Director of the Bone Marrow Transplantation Program. Dave has B.S. and M.S. degrees in Biology from Emory University, an M.D. with Honors, and a Ph.D. in Molecular Genetics and Cell Biology (Virology), both from the University of Chicago.

INOVIO

BARDA

BILL & MELINDA GATES foundation

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Jacqueline Shea, Ph.D.

President & Chief Executive Officer

Dr. Jacqueline Shea has served as INOVIO's President and Chief Executive Officer (CEO) since May 2022. She is responsible for establishing and leading INOVIO's overall corporate strategy across its clinical programs and advancing its DNA medicines platform.

Dr. Shea joined the Company in March 2019 as Chief Operating Officer (COO), serving as a key member of the executive team. She led INOVIO's manufacturing, commercial, business development, project and alliance management operations.

Dr. Shea has more than 25 years of experience in the life sciences and biotech industries. Prior to joining INOVIO, she was the CEO at Aeras, a not-for-profit organization dedicated to developing new vaccines against tuberculosis (TB). Previously, she held executive roles at Emergent BioSolutions and was also the General Manager and Vice President of The Oxford-Emergent Tuberculosis Consortium.

Mark Twyman, MBA

Chief Commercial Officer

Prior to joining INOVIO, Mr. Twyman held key leadership roles including VP Marketing at Novavax, VP Marketing, Pediatric Vaccines at Merck, VP/GM Vaccines at MedImmune and SVP/GM, Biosurgery at Genzyme.

Mr. Twyman earned an MBA in Finance from The Wharton School of the University of Pennsylvania and a Bachelor of Arts degree in Economics from Dickinson College.

Jeffrey Skolnik, M.D.

Senior Vice President, Clinical Development

Dr. Skolnik leads INOVIO's clinical development programs, focusing on HPV and immuno-oncology DNA medicines. He is a key member of the leadership team overseeing these global clinical assets. Dr. Skolnik has held several leadership positions in Clinical Development and Medical Affairs for AstraZeneca, GSK, and TetraLogic Pharmaceuticals, for both early- and late-stage compounds. Dr. Skolnik is a board-certified pediatric hematologist/oncologist and is an adjunct associate professor at the University of Pennsylvania.

Dr. Skolnik holds a B.A. in Biology from the University of Pennsylvania and an MD from New York University.

INOVIO

GlaxoSmithKline

AstraZeneca

Penn
University of Pennsylvania

Roger D. Dansey, M.D.

Chief Medical Officer at Seagen

Dr. Roger Dansey joined Pfizer after the acquisition of Seagen in December 2023 as the Chief Development Officer for Pfizer Oncology focused on late-stage clinical development.

Previously, Dr. Dansey was the Chief Medical Officer at Seagen starting in 2018, where he brought extensive experience in cancer drug development. He was appointed interim CEO from May 2022 until Nov 2022 when he was appointed President, Research and Development. Dr. Dansey's deep oncology background and proven leadership helped Seagen evolve into a global, multi-product oncology company.

Previously, Dr. Dansey was Therapeutic Area Head for Late-Stage Oncology at Merck & Co., Inc., where he was responsible for global registration efforts for Keytruda® (pembrolizumab) across multiple tumor types. Earlier in his career, he was the Vice President of Oncology Clinical Research at Gilead Sciences and the Global Development Lead for Xgeva® (denosumab) at Amgen, where he held multiple roles in oncology and hematology.

Dr. Dansey holds an M.D. from the University of Witwatersrand in Johannesburg, South Africa.

MERCK

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David B. Weiner, Ph.D.

Executive Vice President, Director, Vaccine Center, The Wistar Institute

David Weiner is Executive Vice President of The Wistar Institute, Director of its Vaccine Center, and the W.W. Smith Charitable Trust Endowed Professorship in Cancer Research. The Wistar Institute is the nation's first independent biomedical research institute, NCI-designated Cancer Center, and an international leader in cancer, immunology and infectious disease research. Previously, Dr. Weiner was Professor, Department of Pathology & Laboratory Medicine at the University of Pennsylvania and Chair of the Gene Therapy and Vaccine Program at the University's Perelman School of Medicine and co-leader of the Tumor Virology Program of the Abramson Cancer Center at Penn.

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Previously, Dr. Weiner was Professor, Department of Pathology & Laboratory Medicine at the University of Pennsylvania and Chair of the Gene Therapy and Vaccine Program at the University's Perelman School of Medicine and co-leader of the Tumor Virology Program of the Abramson Cancer Center at Penn.

SCIENTIFIC ADVISORY BOARD

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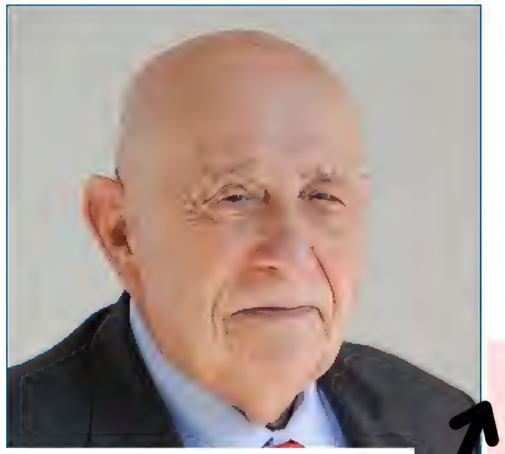
Anthony Ford-Hutchinson, Ph.D.

Former Senior Vice President, Vaccines R&D, Merck

Anthony Ford-Hutchinson has over 30 years of experience in vaccine development and commercialization and was formerly at Merck and Co. During his tenure at Merck, Dr. Ford-Hutchinson played a leadership role in the development of several new blockbuster vaccines, including Gardasil®, Zostavax®, Proquad®, and Rotateq®. He was also responsible for the development of many important Merck drugs, including Singulair®, Arcoxia®, and Isentress® for asthma, pain/inflammation, and the treatment of HIV infection.

Dr. Ford-Hutchinson, who retired from Merck in early 2012, was most recently Senior Vice President, Vaccines Research and Development, and Chairman of the Board of Directors for MSD Wellcome Trust Hilleman Labs. He has held many other prominent positions at Merck in Canada and the USA, including Executive Vice President for Worldwide Research. He was responsible for all strategic decisions in Merck's vaccine R&D following appointment as franchise head in 2005, producing a pipeline with three vaccines in phase III trials and a number of others in earlier development. He obtained his Bachelor's degree in biochemistry from the University of Birmingham, a Master's in molecular enzymology from the University of Warwick, and a Ph.D. in biochemistry from the University of London.



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Stanley A. Plotkin, M.D.

Emeritus Professor, Wistar Institute and University of Pennsylvania; Principal, Vaxconsult

Stanley Plotkin developed the rubella vaccine now used worldwide and has worked extensively on the development and application of other vaccines, including polio, rabies, varicella, rotavirus, and cytomegalovirus. He is Emeritus Professor, Wistar Institute and the University of Pennsylvania, and is a principal of Vaxconsult.

Over the course of his career he has served as senior assistant surgeon with the Epidemic Intelligence Service of the U.S. Public Health Service; Chairman of the Infectious Diseases Committee and the AIDS Task Force of the American Academy of Pediatrics; Chairman of the Microbiology and Infectious Diseases Research Committee of the National Institutes of Health; director of the Division of Infectious Diseases at Children's Hospital of Philadelphia; Associate Chairman of the Department of Pediatrics, University of Pennsylvania; Medical and Scientific Director of Aventis Pasteur; and Executive Advisor to Sanofi Pasteur. Over 600 of his articles have been published, and he has edited several books, including Vaccines, now the standard textbook in the field.

"HUTCHINSON PLAYED A LEADERSHIP ROLE IN THE DEVELOPMENT OF SEVERAL NEW BLOCKBUSTER VACCINES INCLUDING GARDISIL.

MOLNUPIRAVIR

RIDGEBACK BIO

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Molnupiravir

EIDD-2801

Article Talk

From Wikipedia, the free encyclopedia

Molnupiravir, sold under the brand name **Lagevrio**, is an antiviral medication that inhibits the replication of certain RNA viruses.[7] It is used to treat COVID-19 in those infected by SARS-CoV-2.[7] It is taken by mouth.[7]

Molnupiravir is a prodrug of the synthetic nucleoside derivative N^4-hydroxycytidine and exerts its antiviral action by introducing copying errors during viral RNA replication.[13][14]

Molnupiravir was originally developed to treat influenza at Emory University by the university's drug innovation company, Drug Innovation Ventures at Emory (DRIVE), but was reportedly abandoned for mutagenicity concerns.[15][16] It was then acquired by Miami-based company Ridgeback Biotherapeutics, which later partnered with Merck & Co. to develop the drug further.[17]

MOLNUPIRAVIR EIDD-2801

History [edit]

Molnupiravir was developed at Emory University by its drug innovation company, Drug Innovation Ventures at Emory (DRIVE).[17] In 2014, DRIVE began a screening project funded by the Defense Threat Reduction Agency to find an antiviral drug targeting Venezuelan equine encephalitis virus (VEEV), which led to the discovery of EIDD-1931.[33][*unreliable medical source?*] When turned into the prodrug EIDD-2801 (molnupiravir), the compound also showed activity against other RNA viruses including influenza, Ebola, chikungunya, and various coronaviruses.[33]

The international nonproprietary name of the drug was inspired by that of Thor's hammer, Mjölnir. The idea is that the drug will strike down the virus like a mighty blow from the god of thunder.[30]

In 2019, the National Institute of Allergy and Infectious Diseases (NIAID) approved moving molnupiravir into Phase I clinical trials for influenza.[33]

In March 2020, the research team pivoted to studying SARS-CoV-2, and successfully used molnupiravir to treat human cells infected with the novel coronavirus.[33][*unreliable medical source?*] A study found that it is orally active against SARS-CoV-2 in ferrets.[34]

DRIVE then licensed molnupiravir for human clinical studies to Miami-based company Ridgeback Biotherapeutics, which later partnered with Merck & Co. to develop the drug further.[33][17]

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MOLNUPIRAVIR
EIDD-2801

$952M

Economics [edit]

In September 2021, Merck signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) that allows MPP to sublicense molnupiravir and supply the COVID-19 oral medication to 105 low- and middle-income countries. The cost of the US government's initial purchase was about $712 per course of treatment; treatment with generics in developing countries can cost as little as $20.[38][39]

Sales of molnupiravir were $952 million in the fourth quarter of 2021.[40]

Brand names [edit]

Molnupiravir is the international nonproprietary name.[53][54]

Generic versions are available under the brand names Molulife (Mankind),[55] Molena (Emcure),[56] and Esplevir (Promomed).[52]

Public health concerns [edit]

At a November 2021 AMDAC meeting, multiple advisors raised the concern that molnupiravir could accelerate the emergence of variants of concern.[57][58] Other scientists raised similar concerns both before and after the meeting.[59][25][60][24] These concerns were confirmed with the September 2023 publication of a study of 15 million global SARS-CoV-2 sequences: after molnupiravir had been introduced in 2022, genomic changes were more common, especially where it had been used.[26]

MOLNUPIRAVIR
EIDD-2801

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EUA-FDA >

RIDGEBACK BIO

clinical trial(s) summarized in the authorized labeling. Such materials must include any limitations of the clinical trial data as described in the authorized labeling. Merck may not imply that LAGEVRIO is FDA-approved for its authorized use by making statements such as "LAGEVRIO is safe and effective for the treatment of COVID-19."

AA. All descriptive printed matter, advertising, and promotional material, relating to the use of LAGEVRIO under this authorization clearly and conspicuously shall state that:

- LAGEVRIO has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of adults with mild-to-moderate COVID-19, who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate; and

- The emergency use of LAGEVRIO is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

If the Agency notifies Merck that any descriptive printed matter, advertising or promotional materials do not meet the terms set forth in conditions Y through AA of this EUA, Merck must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require Merck to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.11.15 15:41:25 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

b. Moderna[42]

Moderna is a biotechnology company based in the United States that has predominantly focused on development of mRNA therapeutic platforms. It undertook a successful initial public stock offering in 2018. Shortly following the pandemic outbreak, the US government entered into a development and purchase agreement with Moderna for what became its *Spikevax* vaccine, initially for USD 498 million, rising for procurement to approximately USD 10 billion by July 2022. The initial price per dose was approximately USD 16.80 per dose for the first 200 million doses.

The agreement with the US government required Moderna to produce its vaccines within the United States. Based on typical federal government procurement provisions, the US government would receive a nonexclusive license to practice the invention for its own purposes, and the US government secured "march-in" rights for patents secured based on US government funding. This gave the government the right to provide technology to third parties in the event Moderna did not supply vaccines on reasonable terms. (The US government has never exercised its "march-in" rights with respect to a pharmaceutical (including vaccine) product, despite being requested several times by public interest groups.)

Moderna in-licensed mRNA technology from the University of Pennsylvania, paying approximately USD 650 million in royalties (approximately 3.5 percent) by the end of 2021. In addition, Moderna recently agreed to pay USD 400 million ("delayed licensing" fee) to the US National Institutes of Health, Dartmouth College and Scripps Research for patented technology it used to stabilize mRNA-generated spike proteins.

Moderna entered into a large-scale contract manufacturing agreement with Lonza, a Swiss-based manufacturer, with production facilities in both the United States and Switzerland. Moderna licensed its IP to Lonza for purposes of manufacturing the mRNA vaccine, but each party otherwise retained rights in its own IP.

Moderna's "access policy" consisted of announcing that it would not assert its patents in infringement actions against third parties, updating that policy in March 2022 to limit the pledge to 92 Gavi-COVAX Advanced Market Commitment countries.

In December 2020 Moderna concluded an APA with the EU for an initial 80 million doses, with option for an additional 80 million doses, at a price of USD 22.50 per dose, including a nonrefundable down payment of USD 360 million. The EU subsequently expanded that commitment. The EU agreed that it would not obtain any rights in Moderna IP, and it would not export doses outside of Europe without Moderna's consent. Moderna engaged a Spanish manufacturer, ROVI, to perform fill and finish services in Europe, along with Lonza's Swiss manufacturing operation.

Moderna was criticized for delivering only a small percentage of its vaccine doses outside high income countries. It eventually offered doses to COVAX at a tiered price of USD 7–10 per dose.

Moderna is currently involved in litigation with a number of companies regarding entitlement to patented technologies. Among other things, Moderna has asserted that for certain actions arising out of its supply of COVID-19 vaccines it can only be sued as a US government contractor in the Federal Court of Claims, and not otherwise in private civil infringement litigation.[43]

https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf

Moderna in-licensed mRNA technology from the University of Pennsylvania, paying approximately USD 650 million in royalties (approximately 3.5 percent) by the end of 2021. In addition, Moderna recently agreed to pay USD 400 million ("delayed licensing" fee) to the US National Institutes of Health, Dartmouth College and Scripps Research for patented technology it used to stabilize mRNA-generated spike proteins.

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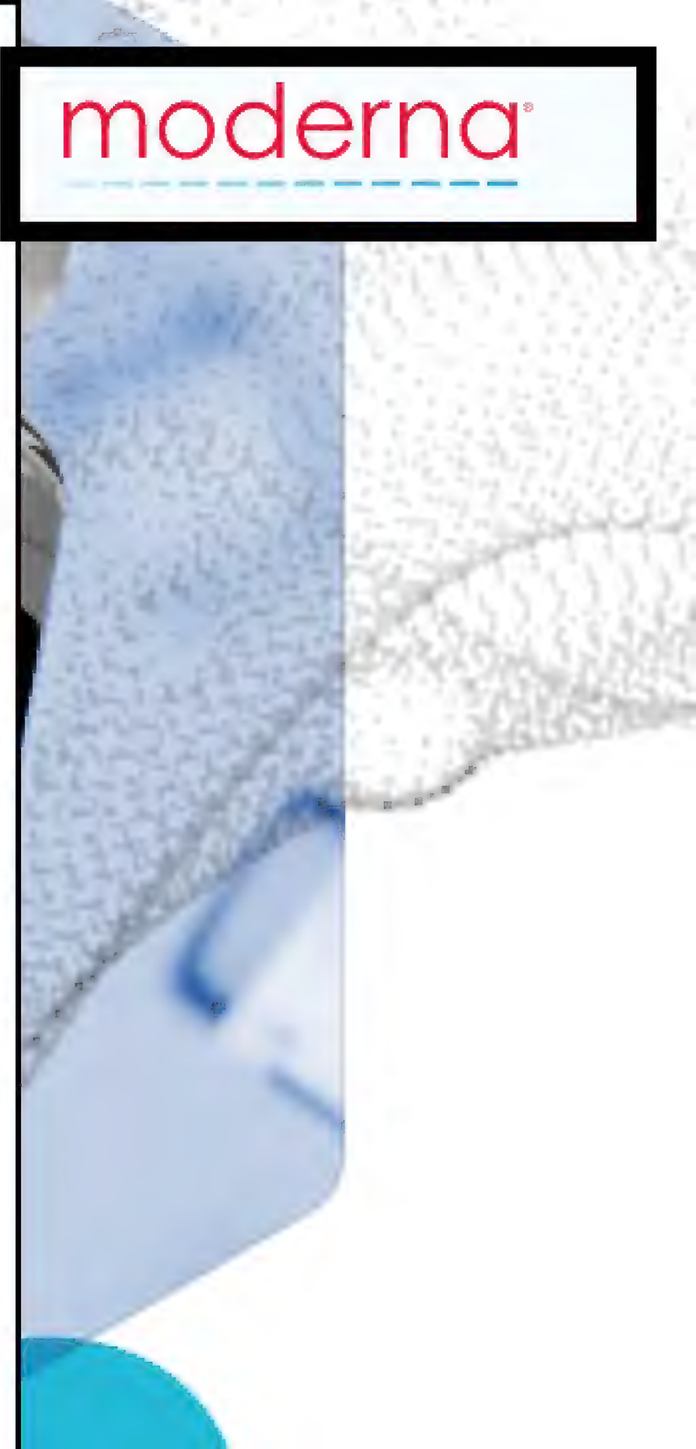

Table 1 identifies several parameters of the 10 vaccine developers and suppliers covered by the study, including the nature of the enterprise, the source of their funding, the underlying vaccine technology, their articulated access policies and the reported price of the vaccines they supplied during the COVID-19 pandemic.

https://www.wipo.int/edocs/pubdocs/en/wipo-pu
rn2023-39-en-intellectual-property-and-technolog
transfer-for-covid-19-vaccines-assessment-of-th
record.p

Table 1 Parameters of the 10 vaccine developers and suppliers covered by the study

	Pfizer/ BioNTech	Moderna	AstraZeneca-Oxford – SII	Johnson & Johnson/ Janssen	Novavax	CureVac	Baylor/ Texas Children's Hospital	PRC – Sinovac; Sinopharm	Gamaleya/ Russian Federation
Type of entity	Private (securities market)	Private (securities market)	Private (securities market/ university)	Private (securities market)	Private (securities market)	Private (securities market)	University (private); hospital (private)	Private/ state owned	State owned
Source of funding	Private market plus APA	US gov't funded development and APA	Foundations (CEPI-Gates); US development and APA; UK development and APA; EU APA	US gov't development and APA	US gov't development and APA; CEPI development and APA	CEPI; German gov't ; EU APA	Self-funded; CEPI (for Dynavax)	Self-funded and government supported	State funded
Vaccine technology	mRNA-based	mRNA-based	Modified adenovirus	Modified adenovirus	Recombinant DNA	mRNA-based (abandoned)	Recombined protein fragment	Inactivated virus	Dual adenovirus vector
Access provisions	Tiered pricing	No patent enforcement pledge	General intent on favorable access for developing countries	Supply at not-for-profit price	Affordable prices	Per CEPI equitable access guidelines	Unknown	Unknown	Unknown
Pricing	US gov't: USD 20–30/dose; EU: EUR 19.5; Peru, Albania, Colombia, Dom. Rep.: USD 12	US gov't: USD 15.25–25.36/dose; EU: USD 22.50, COVAX USD 7–10; Botswana: USD 28.88; Argentina: USD 21.50	EU: EUR 2.9/ dose; UK: (at cost); Brazil: USD 3.16–5.27; Colombia: USD 6, SII-CEPI USD 2.50	US: USD 10/ dose; EU: USD 8.50, COVAX USD 5–8	EU – Denmark: USD 20.90	EU: EUR 10/ dose	India: USD 1.75 (public), USD 3–10 (private)	PRC, both Sinovac and Sinopharm: USD 29.75; Zimbabwe: USD 7, Sinopharm; Hungary: USD 36, Sinovac; Indonesia: USD 17	From USD 9.75 (Guatemala) to USD 27.15 (Pakistan, private)

a. Pfizer/BioNTech[38]

At the earliest stage of the pandemic outbreak, Pfizer, based in the United States, successfully negotiated to acquire rights to mRNA vaccine technology from BioNTech, based in Germany. Pfizer paid BioNTech nearly USD 1 billion for those rights, and agreed to a 50-50 split of gross profits from sales of a resulting vaccine. BioNTech's technology was protected by patents. Pfizer would distribute its vaccine (*Comirnaty*) to most of the world, with BioNTech retaining rights for Germany and Türkiye, and with BioNTech preserving a licensing agreement with a PRC biotechnology company, Fosun, on behalf of the partners (for which Fosun agreed to pay up to USD 85 million in fees and a 35 percent share of gross profits). For reasons which remain unclear, the Pfizer BioNTech vaccine was not introduced in the PRC until quite recently and in limited quantity.

Pfizer and BioNTech entered into a complex Collaboration Agreement that largely gave decision-making control to Pfizer, including with respect to pricing of the vaccines outside Germany and Türkiye. Each party would retain ownership of its solely developed IP, and the parties would jointly own collaboratively developed IP. BioNTech had previously in-licensed mRNA technology from the University of Pennsylvania/Cellscript and Acuitas, each of which received significant royalties based on sales of the vaccine.

Pfizer came into the collaboration with a sophisticated manufacturing and distribution operation within the United States, and most of its manufacturing at least at the initial stages was undertaken in the United States. Unique among the major vaccine developers, Pfizer did not benefit from a technology development agreement with the US government, but it did receive an order for 300 million doses of its vaccine for a total price of USD 5.97 billion in March 2021 (a per dose price of USD 19.90). As of December 2022, the US government had paid more than USD 15 billion to Pfizer/BioNTech for about 655 million doses. As a consequence of going without a development subsidy, the US government did not secure typical Bayh-Dole "march-in" rights with respect to patents from Pfizer.

The European Union (EU) also entered into a large-scale APA in November 2020 with Pfizer/BioNTech, for up to 300 million doses at a price of EUR 19.5 per dose. Pfizer/BioNTech entered into a number of additional agreements to supply other countries, including Peru, Colombia, the Dominican Republic and Albania. The price per dose in each of these contracts was USD 12, without firm commitment on delivery schedule. Pfizer/BioNTech would retain ownership of all IP. Note that Pfizer's agreements with the US government did not require it to supply LMICs at preferential prices.

Pfizer's chief executive officer (CEO) objected to the proposal for a WTO TRIPS waiver, arguing that Pfizer was limited in its supply capacity by shortages of component materials, and that opening up the supply market to more potential producers would exacerbate the problem. He also suggested that LMICs were reluctant to purchase the mRNA vaccine because of cold chain storage limitations.[39]

There is no evidence suggesting that Pfizer/BioNTech affirmatively threatened any party with patent infringement litigation intended to block production during the course of the pandemic. It is currently involved in litigation with Moderna, among others, regarding rights to patented technologies.[40] The litigation with Moderna – which Moderna initiated in the United States and Germany – has been extending to additional jurisdictions, including Belgium, Ireland and the United Kingdom. Pfizer and BioNTech have counterclaimed.[41]

https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf

Safety, tolerability, pharmacokinetics, and immunogenicity of the therapeutic monoclonal antibody mAb114 targeting Ebola virus glycoprotein (VRC 608): an open-label phase 1 study

*Martin R Gaudinski, Emily E Coates, Laura Novik, Alicia Widge, Katherine V Houser, Eugeania Burch, LaSonji A Holman, Ingelise J Gordon, Grace L Chen, Cristina Carter, Martha Nason, Sandra Sitar, Galina Yamshchikov, Nina Berkowitz, Charla Andrews, Sandra Vazquez, Carolyn Laurencot, John Misasi, Frank Arnold, Kevin Carlton, Heather Lawlor, Jason Gall, Robert T Bailer, Adrian McDermott, Edmund Capparelli, Richard A Koup, John R Mascola, Barney S Graham, Nancy J Sullivan, Julie E Ledgerwood, on behalf of the VRC 608 Study team**

Summary

Background mAb114 is a single monoclonal antibody that targets the receptor-binding domain of Ebola virus glycoprotein, which prevents mortality in rhesus macaques treated after lethal challenge with *Zaire ebolavirus*. Here we present expedited data from VRC 608, a phase 1 study to evaluate mAb114 safety, tolerability, pharmacokinetics, and immunogenicity.

Methods In this phase 1, dose-escalation study (VRC 608), conducted at the US National Institutes of Health (NIH) Clinical Center (Bethesda, MD, USA), healthy adults aged 18–60 years were sequentially enrolled into three mAb114 dose groups of 5 mg/kg, 25 mg/kg, and 50 mg/kg. The drug was given to participants intravenously over 30 min, and participants were followed for 24 weeks. Participants were only enrolled into increased dosing groups after interim safety assessments. Our primary endpoints were safety and tolerability, with pharmacokinetic and anti-drug antibody assessments as secondary endpoints. We assessed safety and tolerability in all participants who received study drug by monitoring clinical laboratory data and self-report and direct clinician assessment of prespecified infusion-site symptoms 3 days after infusion and systemic symptoms 7 days after infusion. Unsolicited adverse events were recorded for 28 days. Pharmacokinetic and anti-drug antibody assessments were completed in participants with at least 56 days of data. This trial is registered with ClinicalTrials.gov, number NCT03478891, and is active but no longer recruiting.

Findings Between May 16, and Sept 27, 2018, 19 eligible individuals were enrolled. One (5%) participant was not infused because intravenous access was not adequate. Of 18 (95%) remaining participants, three (17%) were assigned to the 5 mg/kg group, five (28%) to the 25 mg/kg group, and ten (55%) to the 50 mg/kg group, each of whom received a single infusion of mAb114 at their assigned dose. All infusions were well tolerated and completed over 30–37 min with no infusion reactions or rate adjustments. All participants who received the study drug completed the safety assessment of local and systemic reactogenicity. No participants reported infusion-site symptoms. Systemic symptoms were all mild and present only in four (22%) of 18 participants across all dosing groups. No unsolicited adverse events occurred related to mAb114 and one serious adverse event occurred that was unrelated to mAb114. mAb114 has linear pharmacokinetics and a half-life of 24·2 days (standard error of measurement 0·2) with no evidence of anti-drug antibody development.

Interpretation mAb114 was well tolerated, showed linear pharmacokinetics, and was easily and rapidly infused, making it an attractive and deployable option for treatment in outbreak settings.

Funding Vaccine Research Center, US National Institute of Allergy and Infectious Diseases, and NIH.

Lancet 2019; 393: 889–98

Published Online January 24, 2019 http://dx.doi.org/10.1016/S0140-6736(19)30036-4

This online publication has been corrected. The corrected version first appeared at thelancet.com on May 28, 2020

See Comment page 850

*Listed at the end of the Article

Vaccine Research Center (M R Gaudinski MD, E E Coates PhD, L Novik MA, A Widge MD, K V Houser PhD, E Burch MPH, L A Holman I-NP, I J Gordon RN, G L Chen MD, C Carter MD, S Sitar MS, G Yamshchikov MS, N Berkowitz MPH, C Andrews MS, S Vazquez MS, C Laurencot PhD, J Misasi MD, F Arnold PhD, K Carlton MBA, H Lawlor MS, J Gall PhD, R T Bailer PhD, Prof A McDermott PhD, Prof R A Koup MD, Prof J R Mascola MD, Prof B S Graham MD, Prof N J Sullivan PhD, Prof J E Ledgerwood DO) and Biostatistics Research Branch, Division of Clinical Research (M Nason PhD), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA; and School of Medicine and Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California San Diego, San Diego, CA, USA (Prof E Capparelli PharmD)

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Introduction

Ebolaviruses are negative-strand RNA viruses with five species,[1,2] three of which are known to induce haemorrhagic fever in humans: *Bundibugyo ebolavirus*, *Sudan ebolavirus*, and *Zaire ebolavirus* (EBOV).[3] Outbreaks probably begin by zoonotic transmission to humans after exposure to fruit bats or other infected animals which spread through the community by direct contact with blood, bodily fluids, or organs of infected people or corpses.[4–7] Ebola virus disease becomes symptomatic after a 2–21 day incubation period and causes severe systemic illness characterised by fever, fatigue, myalgia, headache, pharyngitis, vomiting, diarrhoea, rash, kidney and liver dysfunction, and bleeding diathesis, with case fatality rates ranging from 25–90%.[5,8] The 2014 west Africa EBOV outbreak, in which the first case was reported in December, 2013, and the last case in June, 2016, was the largest outbreak to date, with

JANUARY 2019

mAb114 phase 1 study was funded by NIH's Vaccine Research Center [VRC]

Scientists involved:

JOHN MASCOLA-

EMILY COATES-

BARNEY GRAHAM-

NANCY SULLIVAN- IS A SENIOR INVESTIGATOR AND CHIEF OF THE **BIODEFENSE RESEARCH** SECTION AT THE **VACCINE RESEARCH CENTER**. HER TEAM DISCOVERED THE MONOCLONAL ANTIBODY **MAB114**. FOLLOWING HER WORK ON HIV, SULLIVAN PURSUED POSTDOCTORAL TRAINING UNDER THE GUIDANCE OF **GARY NABEL**, STUDYING THE MECHANISMS OF EBOLA VIRUS PATHOGENESIS AND IMMUNE PROTECTION.

JULIE LEDGERWOOD-

frontiers in Immunology

Front Immunol. 2021; 12: 721328.
Published online 2021 Aug 30. doi: 10.3389/fimmu.2021.721328

PMCID: PMC8435780
PMID: 34526994

Journal Article

Review: Insights on Current FDA-Approved Monoclonal Antibodies Against Ebola Virus Infection

Olivier Tshiani Mbaya,[1,*] Philippe Mukumbayi,[2] and Sabue Mulangu[3]

Author information · Article notes · Copyright and License information PMC Disclaimer

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This article was submitted to Vaccines and Molecular Therapeutics, a section of the journal Frontiers in Immunology

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8435780/

Ebola outbreak treatment trial narrowed to two promising drugs

Lisa Schnirring | News Editor | CIDRAP News, August 12, 2019

Topics: Ebola , Viral Hemorrhagic Fever

SHARE

Global health officials today announced a pause in the clinical trial of four investigational Ebola drugs in the Democratic Republic of Congo (DRC) outbreak region after an early look at the data found that two of the drugs—Regeneron and mAb 114—stood out as more effective.

In other outbreak developments, the DRC reported 38 more cases since Aug 9, lifting the outbreak total past 2,800 to 2,831.

Latest outbreak numbers

In updates to the WHO's Ebola dashboard, the DRC reported 8 more cases on Aug 10, 15 more on Aug 11, and 15 more cases today, putting the overall total at 2,831.

Health officials are still investigating 326 suspected infections.

Since Aug 9, 21 more people died from the disease, lifting the fatality count to 1,888.

https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs

Journal of Exposure Science & Environmental Epidemiology www.nature.com/jes

ARTICLE OPEN

Check for updates

The size and culturability of patient-generated SARS-CoV-2 aerosol

Joshua L. Santarpia[1,2,3,11✉], Vicki L. Herrera[1,2], Danielle N. Rivera[3], Shanna Ratnesar-Shumate[1,2], St. Patrick Reid[1,2,11], Daniel N. Ackerman[3], Paul W. Denton[4], Jacob W. S. Martens[4], Ying Fang[5], Nicholas Conoan[6], Michael V. Callahan[7], James V. Lawler[2,8], David M. Brett-Major[2,9] and John J. Lowe[2,10,11]

BACKGROUND: Aerosol transmission of COVID-19 is the subject of ongoing policy debate. Characterizing aerosol produced by people with COVID-19 is critical to understanding the role of aerosols in transmission.
OBJECTIVE: We investigated the presence of virus in size-fractioned aerosols from six COVID-19 patients admitted into mixed acuity wards in April of 2020.
METHODS: Size-fractionated aerosol samples and aerosol size distributions were collected from COVID-19 positive patients. Aerosol samples were analyzed for viral RNA, positive samples were cultured in Vero E6 cells. Serial RT-PCR of cells indicated samples where viral replication was likely occurring. Viral presence was also investigated by western blot and transmission electron microscopy (TEM).
RESULTS: SARS-CoV-2 RNA was detected by rRT-PCR in all samples. Three samples confidently indicated the presence of viral replication, all of which were from collected sub-micron aerosol. Western blot indicated the presence of viral proteins in all but one of these samples, and intact virions were observed by TEM in one sample.
SIGNIFICANCE: Observations of viral replication in the culture of submicron aerosol samples provides additional evidence that airborne transmission of COVID-19 is possible. These results support the use of efficient respiratory protection in both healthcare and by the public to limit transmission.

Keywords: SARS-CoV-2; aerosol transmission; viral aerosol; human-generated aerosol

Journal of Exposure Science & Environmental Epidemiology; https://doi.org/10.1038/s41370-021-00376-8

Michael Callahan

+

James Lawler

James V Lawler

Dr. James V. Lawler MD

Infectious Disease | **Nebraska Medicine-Nebraska Medical Center**

Overview

Dr. James V. Lawler is an infectious disease specialist in Omaha, Nebraska and is affiliated with Nebraska Medicine-Nebraska Medical Center. He received his medical degree from Georgetown University School of Medicine and has been in practice for more than 20 years. Dr. James V. Lawler accepts Medicare, Humana, Blue Cross - see other insurance plans accepted.

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UNMC

Global Center for Health Security

FORT DETRICK

Before his arrival at the University of Nebraska Medical Center in 2018, Dr. Lawler served as a Navy commander and was chief of clinical biodefense research at the Naval Medical Research Center in Fort Detrick, MD.

He was an attending physician at Walter Reed National Military Medical Center and served White House assignments as Homeland Security Council and National Security Council staff, where he worked on biodefense, pandemic response, and health preparedness.

Dr. Lawler has field experience treating Ebola patients in sub-Saharan Africa, and he served as a subject matter expert in the training of Department of Defense medical personnel working with infectious diseases patients.

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https://health.usnews.com/doctors/james-lawler-308105

https://www.unmc.edu/healthsecurity/about/leadership/james-lawler.html

https://advancingcures.org/vic-management-michael-callahan/

Prior Experience

Before coming to MGH, Dr. Callahan was director of the U.S. Agency for International Development (USAID) clinical research programs in Nigeria, DRC (then Zaire) and Ghana. His research focus was congenital malaria, dengue and chikungunya immune convalescent syndrome and filovirus infections (Ebola and Marburg). He has authored over 50 peer-reviewed papers, including 9 U.S. Government guidance documents for infectious disease investments, and 15 chapters in leading textbooks of Medicine and Infectious Diseases, 8 US and international patents for medical advances and has served on over 20 Presidential Commissions or Institute of Medicine Working Groups for Zika, Ebola, Pandemic and Avian Influenza, Biodefense Redirection of FSU Biological Weapons, International drug counterfeiting and the advancement of low cost biologics for low and middle income nations. Dr. Callahan is the recipient of numerous international awards including the Secretary of Defense Award for

Academic Credentials

- BS; Toxicology (1) Microbiology (2) University of Massachusetts at Amherst
- MD; University of Alabama School of Medicine
- Medical Residency & Chief Medical Resident; Tuft-New England Medical Center Hospital
- Fellowship Training; University of Colorado Health Sciences and National Jewish Hospital, Denver, Colorado (Board-certified in Infectious Diseases & Internal Medicine)
- Diplomat: Tropical Medicine and Hygiene: Royal Society of Physicians

CENTRAL INTELLIGENCE AGENCY

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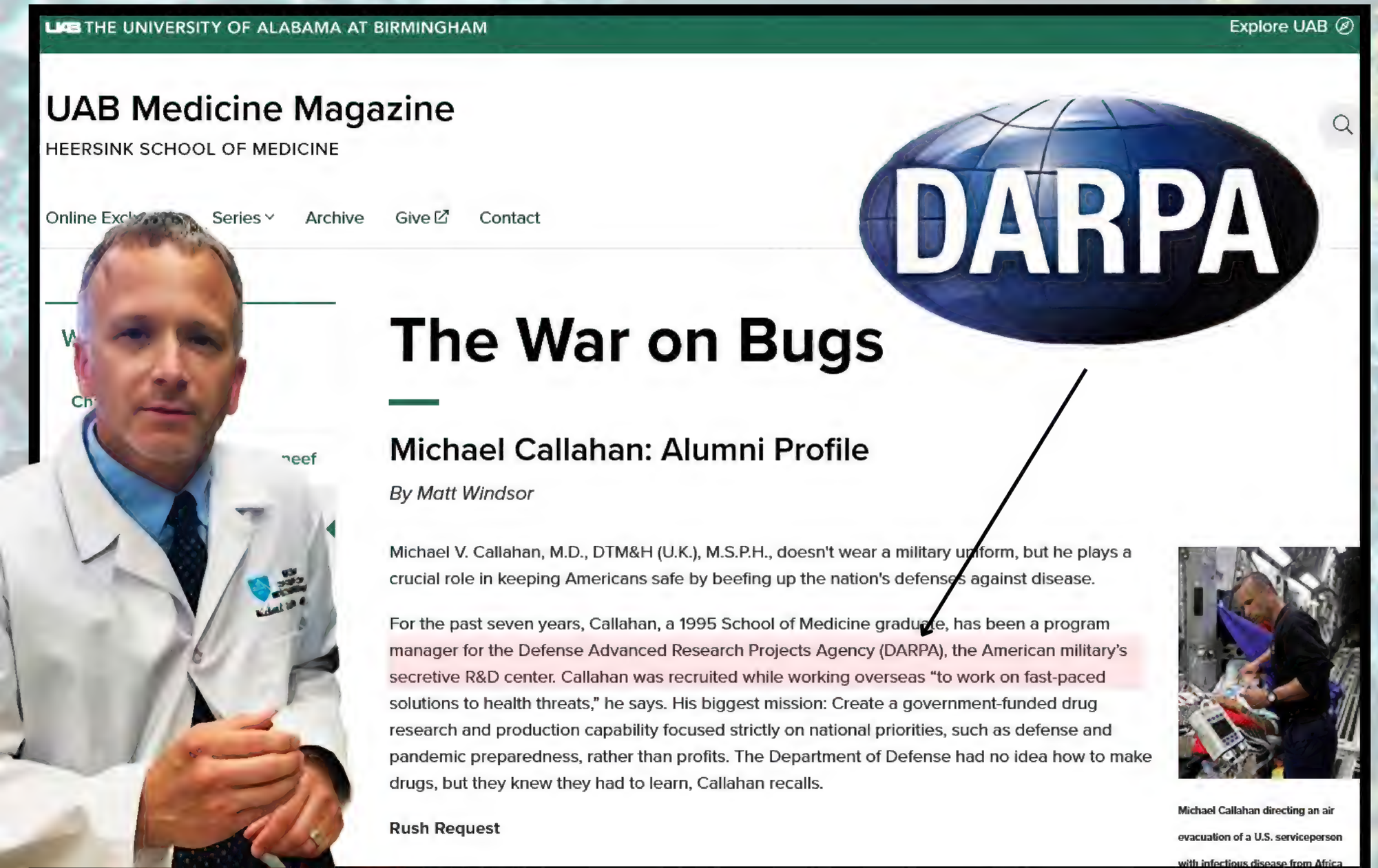
MICHAEL V. CALLAHAN



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DARPA

The War on Bugs

Michael Callahan: Alumni Profile

By Matt Windsor

Michael V. Callahan, M.D., DTM&H (U.K.), M.S.P.H., doesn't wear a military uniform, but he plays a crucial role in keeping Americans safe by beefing up the nation's defenses against disease.

For the past seven years, Callahan, a 1995 School of Medicine graduate, has been a program manager for the Defense Advanced Research Projects Agency (DARPA), the American military's secretive R&D center. Callahan was recruited while working overseas "to work on fast-paced solutions to health threats," he says. His biggest mission: Create a government-funded drug research and production capability focused strictly on national priorities, such as defense and pandemic preparedness, rather than profits. The Department of Defense had no idea how to make drugs, but they knew they had to learn, Callahan recalls.

Rush Request

Michael Callahan directing an air evacuation of a U.S. serviceperson with infectious disease from Africa

CENTRAL INTELLIGENCE AGENCY

UNITED STATES OF AMERICA

ALEX AZAR

Alex Azar

Article Talk

From Wikipedia, the free encyclopedia

Alex Michael Azar II (/ˈeɪzɑːr/; born June 17, 1967) is an American attorney, businessman, lobbyist, and former pharmaceutical executive who served as the U.S. Secretary of Health and Human Services from 2018 to 2021. Azar was nominated to his post by President Donald Trump on November 13, 2017, and confirmed by the United States Senate on January 24, 2018. He was also chairman of the White House Coronavirus Task Force from its inception in January 2020 to February 2020, when he was replaced by Vice President Mike Pence.

Personal details	
Born	Alex Michael Azar II June 17, 1967 (age 56) Johnstown, Pennsylvania, U.S.
Political party	Republican
Spouse	Jennifer Reist[1]
Children	2
Education	Dartmouth College (BA) Yale University (JD)
Occupation	Politician · attorney · businessman · lobbyist · former pharmaceutical executive

Alex Azar

Official portrait, 2019

U.S. Department of Health and Human Services
Enhancing the health and well-being of all Americans

ALEX AZAR

Alex Azar

Official portrait, 2019

Eli Lilly and Company [edit]

In June 2007, Azar was hired by Eli Lilly and Company chief executive officer Sidney Taurel to be the company's top lobbyist and spokesman as its senior vice president of corporate affairs and communications.[7][20] Azar left the position after the 2008 United States presidential election was won by Democratic Party

In April 2009, Azar became vice president of Lilly's U.S. Managed Healthcare Services organization and its Puerto Rico affiliate.[21] In 2009, the company paid $1.415 billion to settle criminal charges regarding its promotion of antipsychotic drug Zyprexa (olanzapine) for off-label uses between 1999 and 2005.[20]

Effective January 1, 2012, Azar became president of Lilly USA, LLC, the largest division of Eli Lilly and Company, and was responsible for the company's entire operations in the United States.[21] Prices for drugs rose substantially under Azar's leadership, including the tripling of the cost of the company's top-selling insulin drug. Also under Azar's watch, Eli Lilly was one of three companies accused in a class-action lawsuit of exploiting the drug pricing system to increase profits for insulin. Eli Lilly was also fined in Mexico for colluding on the price of insulin.[22][23]

In connection with the position, Azar served on the board of directors of the Biotechnology Innovation Organization, a pharmaceutical lobby.[24]

In January 2017, Azar resigned from Eli Lilly "to pursue other career opportunities" as a result of a company reorganization.[25] He also resigned from the board of directors of the Biotechnology Innovation Organization. In his last year at the corporation he earned $2 million.[26]

DARPA

More

The Defense Advanced Research Projects Agency (DARPA) is a research and development agency of the United States Department of Defense.

Formed	February 7, 1958 (as ARPA)
Headquarters	Arlington County, Virginia, U.S.
Employees	220

DARPA was initiated on February 7, 1958 by President Dwight D. Eisenhower in response to the Soviet launching of Sputnik 1 in 1957 [2] [3]. Originally known as the Advanced Research Projects Agency (ARPA), the agency was created to facilitate research in technology with potential military applications [3].

1	Spanish flu	Influenza A/H1N1	17–100 million	1–5.4% of global population[5]	1918–1920	Worldwide
10	1918–1922 Russia typhus epidemic	Typhus	2–3 million	1–1.6% of Russian population[15]	1918–1922	Russia
11	1957–1958 influenza pandemic	Influenza A/H2N2	1–4 million	–	1957–1958	Worldwide
12	Hong Kong flu	Influenza A/H3N2	1–4 million	–	1968–1969	Worldwide
3	**HIV/AIDS pandemic**	**HIV/AIDS**	**43 million (as of 2024)**	[a]	**1981–present**[7]	**Worldwide**
5	**COVID-19 pandemic**	**COVID-19**	**7–35 million**[9][10] **(as of 2024)**	[a]	**2019**[b]**–present**[11][12][c]	**Worldwide**

Frank Kendall III

Article Talk

From Wikipedia, the free encyclopedia

Frank Kendall III (born January 26, 1949) is an American engineer, lawyer and executive who is the 26th and current United States Secretary of the Air Force. He has served in several senior positions in the U.S. Department of Defense.[1] A West Point graduate (Class of 1971, Distinguished Graduate),[2] he retired as a lieutenant colonel from the U.S. Army Reserve. From 2011 to 2017, Kendall served as the Under Secretary of Defense for Acquisition, Technology and Logistics in the Obama Administration.[3][4][5][2] He is a member of the Democratic Party.

U.S. ARMY

GEORGETOWN UNIVERSITY

Kendall during his tenure as acting Deputy Director, 1989

Kendall began his career as a U.S. Army officer. After several assignments including postings to Germany and teaching engineering at West Point, he joined the civil service working as a systems engineer in missile defense. In 1986, he became the Assistant Deputy Under Secretary for Strategic Defense Systems as a member of the Senior Executive Service. From 1989 to 1994, he served as acting and then permanent Deputy Director of Defense Research and Engineering with responsibility for all U.S. conventional weapon systems research and development programs. After leaving government service in 1994, Kendall served as Corporate Vice President of Engineering at Raytheon and later as a consultant. During this period, Kendall acquired a J.D. degree from Georgetown University Law Center and worked on a pro bono basis as a human rights attorney.[6]

DARPA

Frank Kendall

26th United States Secretary of the Air Force

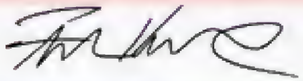
Incumbent

Assumed office
July 28, 2021

President	Joe Biden
Deputy	Gina Ortiz Jones Kristyn E. Jones (acting)
Preceded by	Barbara Barrett

Frank Kendall III

During his tenure as Under Secretary, Kendall implemented policies that led to substantial improvements in the cost and schedule performance of the Defense Department's weapons acquisition programs.[8] In 2016, he was recognized as Person of the Year by Aviation Week and Space Technology for his cost control efforts.[9] In addition to the policy changes he initiated and executed under the "Better Buying Power" initiatives he directly oversaw over 50 of the largest defense weapons programs. Examples include the F-35 Joint Strike Fighter program where he froze production for two years to incentivize efforts to stabilize the design,[10] the GPS 3 ground system, OCX, where he led the effort to restructure and complete this troubled program.[11] He oversaw the initiation of the development of the B-21 Long Range Strike Bomber which is currently executing to plan.[12] He formulated and led the effort to acquire the Military Health System GENESIS (MHS GENESIS) program, modern healthcare management system that has been adopted by the Department of Veterans Affairs as well as the Defense Department.[13][14] Kendall led the effort to support operations in Iraq and Afghanistan[15][16][17] with rapid acquisition programs and he led the effort to remove Syrian chemical weapons from that country and destroy them at sea.[18] Kendall was a major sponsor for innovation,[19] launching the Defense Advanced Research Projects Agency led Aerospace Innovation Initiative.[20] He raised alarms about Chinese military modernization and the threat it posed to U.S. conventional military superiority.[21] While in office he authored the articles on defense acquisition that he compiled in his book "Getting Defense Acquisition Right".[22]

Preceded by	Ash Carter
Succeeded by	Ellen Lord
Personal details	
Born	January 26, 1949 (age 75) Pittsfield, Massachusetts, U.S.
Political party	Democratic
Education	United States Military Academy (BS) California Institute of Technology (MS) Long Island University (MBA) Georgetown University (JD)
Signature	
Military service	
Branch/service	U.S. Army Reserve
Rank	Lieutenant colonel

U.S. ARMY

DARPA

GEORGETOWN UNIVERSITY

Frank Kendall III

which is currently executing to plan.[12] He formulated and led the effort to acquire the Military Health System GENESIS (MHS GENESIS) program, modern healthcare management system that has been adopted by the Department of Veterans Affairs as well as the Defense Department.[13][14] Kendall led the effort to support operations in Iraq and Afghanistan[15][16][17] with rapid acquisition programs and he led the effort to remove Syrian chemical weapons from that country and destroy them at sea.[18] Kendall was a major sponsor for innovation,[19] launching the Defense Advanced Research Projects Agency led Aerospace Innovation Initiative.[20] He raised alarms about Chinese military modernization and the threat it posed to U.S. conventional military superiority.[21] While in office he authored the articles on defense acquisition that he compiled in his book "Getting Defense Acquisition Right".[22]

Biden Administration [edit]

On April 27, 2021, President Joe Biden announced Kendall as his nominee to be the 26th Secretary of the Air Force.[23] His Senate confirmation occurred after almost three months of deliberation, due to holds by Senators Mike Lee,[24] Gary Peters[25] and Elizabeth Warren,[26] the latter of whom released her hold after Kendall agreed to extend his post-governmental recusal agreements from two to four years.[26] Kendall was eventually confirmed by voice vote on June 26, 2021,[27][28] administratively sworn in on July 28, 2021[29] and ceremonially sworn in by Secretary of Defense Lloyd Austin on August 4, 2021.[30]

OWS SPENT 1.5 BILLION ON MODERNA TO PROVIDE A C19 "VACCINE"

moderna

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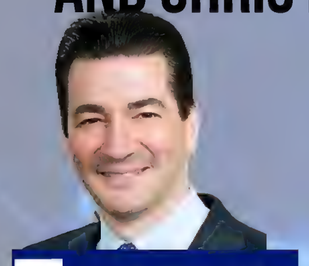
MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION

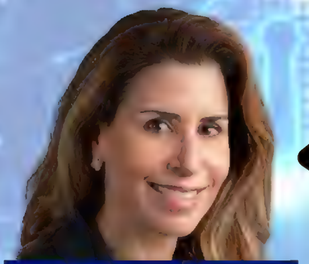
AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN

NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.

FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN. ADDITIONALLY BORIO IS VP OF IN-Q-TEL.

ALSO ON THE BOARD FOR RESILIENCE IS FORMER FDA COMMISSIONER SCOTT GOTTLIEB AND CHRIS DARBY PRESIDENT OF IN-Q-TEL

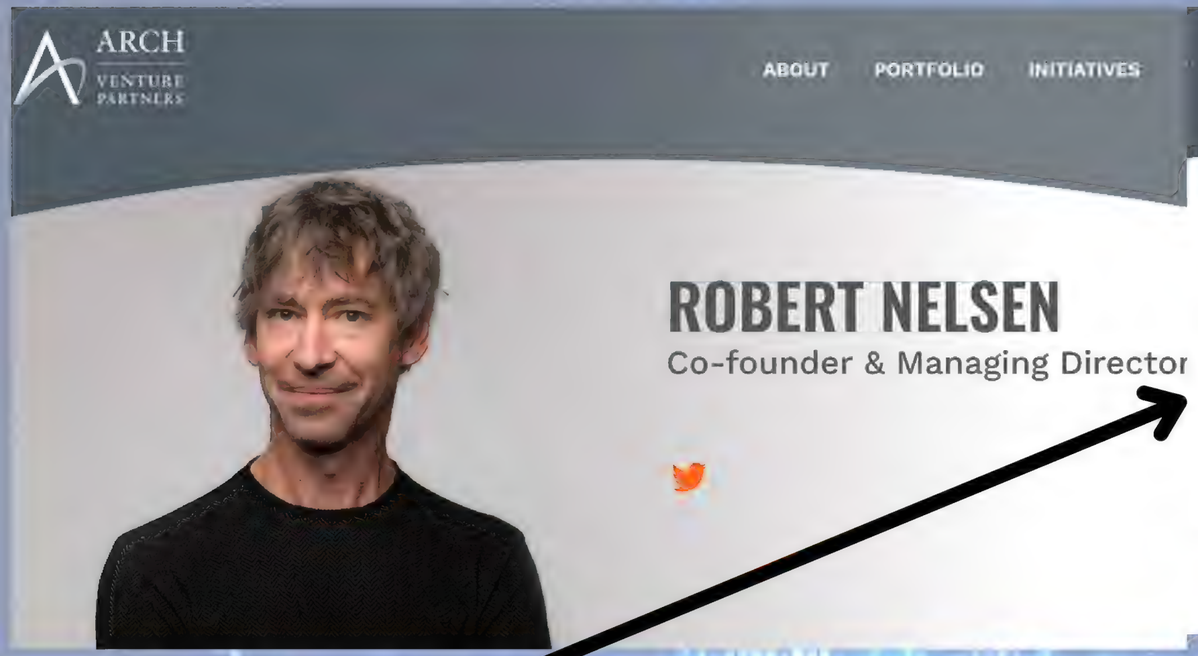


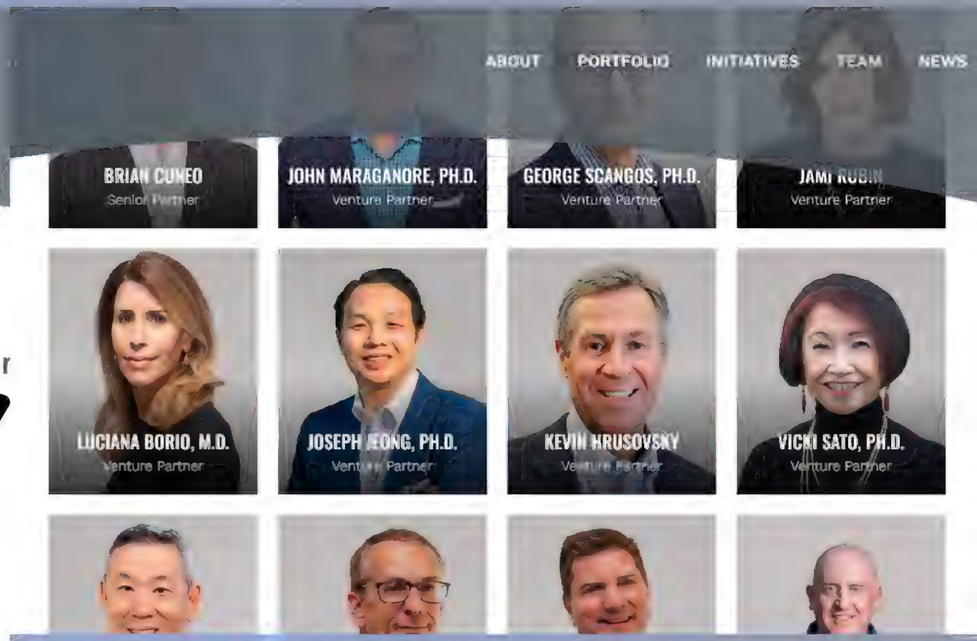


ALSO ON THE BOARD IS JOE LONSDALE, FOUNDER OF PALANTIR

PALANTIR WAS FUNDED BY IN-Q-TEL

PALANTIR CREATED THE TIBERIUS PROGRAM WHICH WAS THE SOFTWARE THAT RAN OWS





BORIO ON THE BOARD FOR NELSEN'S COMPANY ARCH

RESILIENCE ADMITS TO WORKING WITH THE DOD VIA THE JPEO-CBRN

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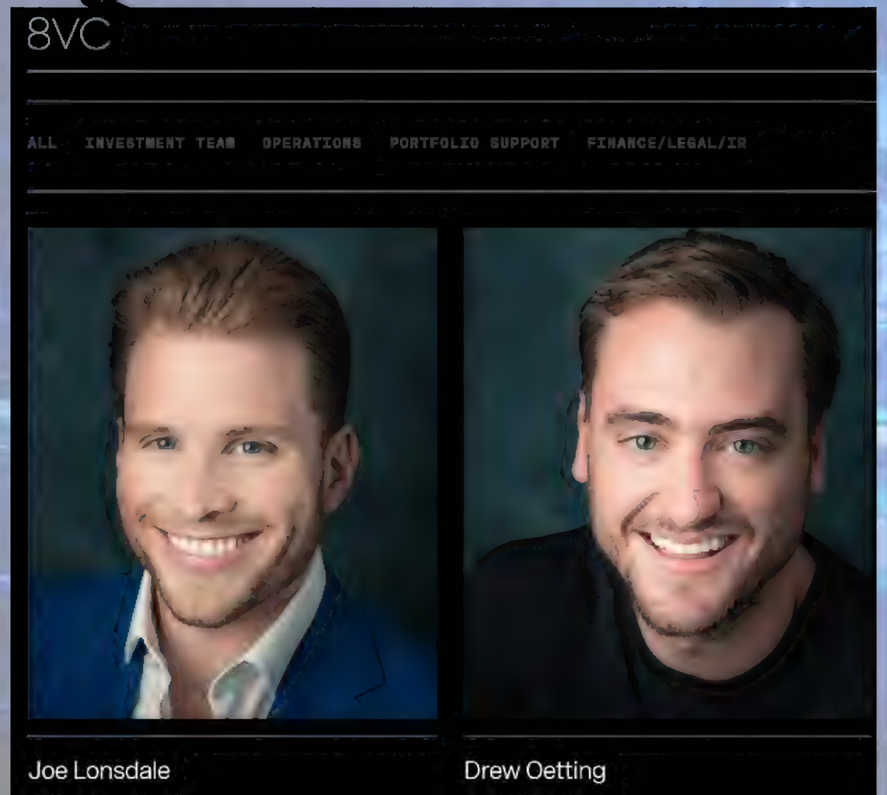
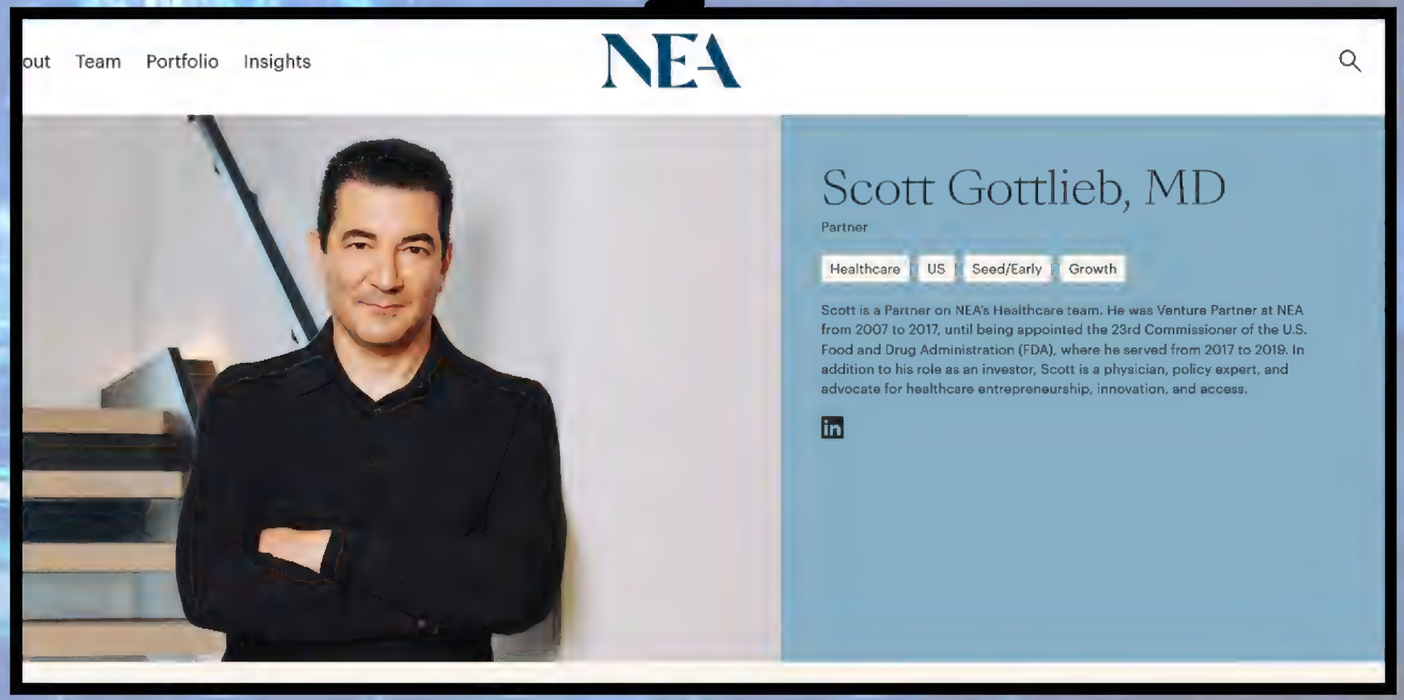
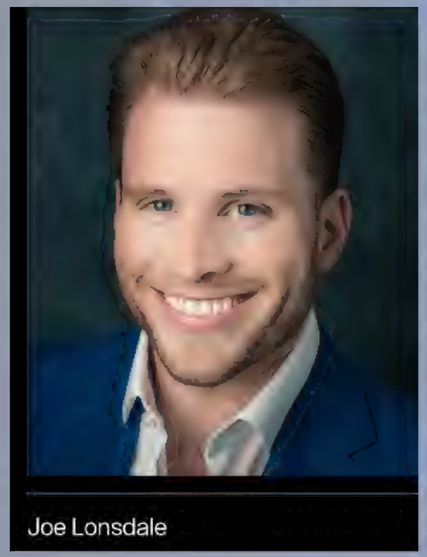






Joe Lonsdale founded Palantir.

Palantir created the software for Operation Warp Speed

Palantir

OPERATION WARP SPEED

HTTPS://FEDSCOOP.COM/TAG/TIBERIUS/

FEDSCOOP

ACQUISITION

HHS renews, expands Palantir's Tiberius contract to $31M

The scope of the COVID-19 vaccine distribution platform has grown and with it the price tag.

BY DAVE NYCZEPIR • JULY 26, 2021

The Department of Health and Human Services renewed and expanded its one-year contract for its COVID-19 vaccine distribution platform Tiberius from nearly $17 million to $31 million, tech company Palantir announced Monday.

Palantir Foundry powers Tiberius, which has grown from simply helping HHS understand vaccine distribution across the U.S. and providing an integrated view of the supply chain to serving as the backbone of day-to-day dosage programs launched by agencies like the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority.

HHS had Palantir develop Tiberius in mid-2020 as part of the Trump administration's Operation Warp Speed, which has since been rebranded as the Countermeasure Acceleration Group.

Board of Directors

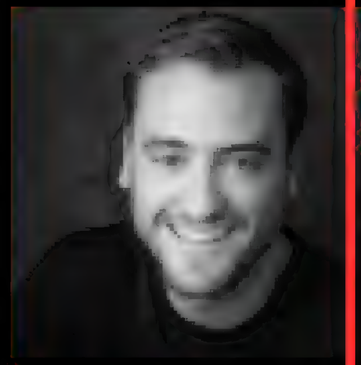
RESILIENCE

Robert Nelsen

Chairman and Founder, ARCH

Patrick Y. Yang, PhD

Vice Chairman, Former EVP Juno, Roche, Genentech

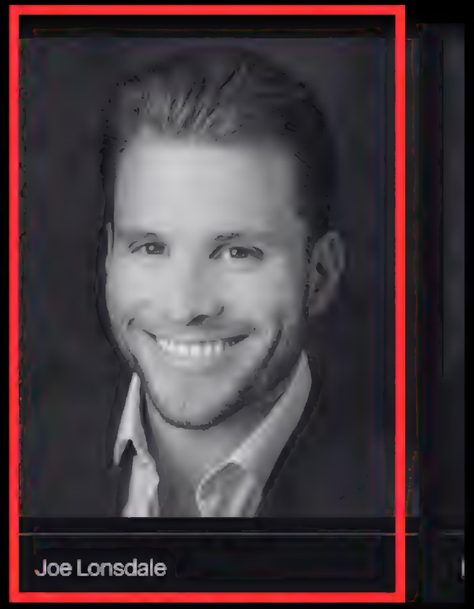


Drew Cetting

Co-founder & President, BVC, Co-founder Affinity

Rahul Singhvi, SoD

Co-founder, CEO



Joe Lonsdale

Frances Arnold, PhD

Nobel Prize Laureate, CalTech Professor

George Barrett

Former Chairman & CEO, Cardinal Health

Mitchell E. Daniels, Jr.

President, Purdue University, Former Governor of Indiana

Chris Darby

CEO, In-Q-Tel

ALL HIGHLIGHTED INDIVIUALS HAVE TIES TO THE INTELLIGENCE COMMUNITY

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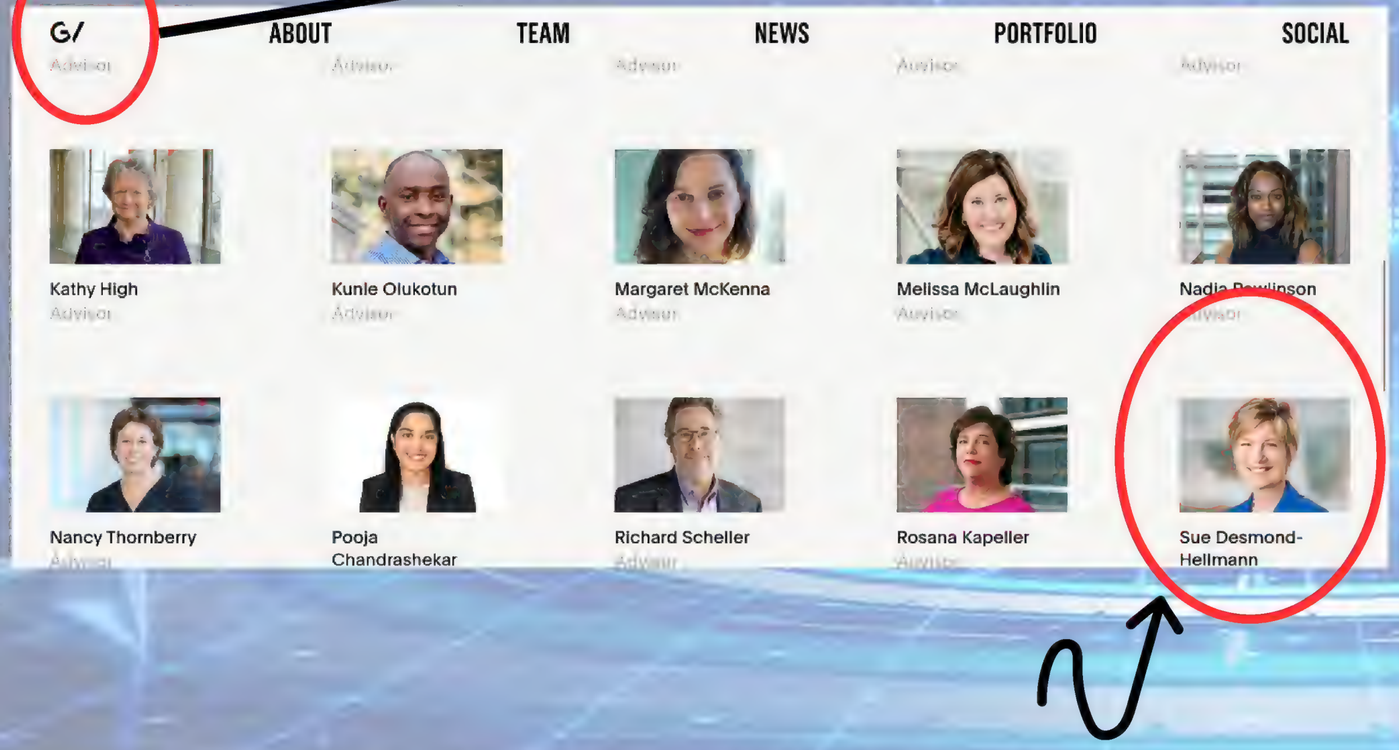
GV = GOOGLE VENTURES
FORMER BILL & MELINDA GATES FOUNDATION CEO AND CURRENT BOARD MEMBER OF: RESILIENCE AND PFIZER,



Launched as Google Ventures in 2009, GV originated as an independent venture capital firm for innovative founders. While today we're formally known as GV, our previous moniker (Google Ventures) is the root of our DNA. With Alphabet as our sole limited partner, we focus all our energy on meeting and supporting founders at the earliest stages of company-building. GV's operating partners work to support startups across design, equity, diversity & inclusion, talent, and engineering. GV also helps startups interface with Google, providing unique access to the world's best technology and talent.

GV operates on long time horizons and deals in decades — not rounds. At launch, we had a $60 million capital commitment and a desire to partner with founders moving the world forward. Today, GV has over $10 billion in assets under management, 400 active portfolio companies across North America and Europe, and notable investment outcomes including Uber, Nest, Slack, GitLab, Duo Security, Flatiron Health, Verve Therapeutics, and One Medical.

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Freda Lewis-Hall, MD,

Scott Gottlieb, MD

Frances Arnold, PhD

Pfizer

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Dr. Freda Lewis-Hall Joins Pfizer As Chief Medical Officer

Monday, May 04, 2009 - 06:46am

Prominent Physician, Researcher and Business Leader Will Direct Global Medical and Regulatory Strategy, Join Executive Leadership Team

(BUSINESS WIRE)--Pfizer Inc announced today that Freda Lewis-Hall, M.D., has been appointed as Chief Medical Officer and Senior Vice President, Pfizer Inc. Dr. Lewis-Hall will be the senior physician in the company, responsible for enterprise-wide medical, patient safety, regulatory affairs and quality assurance as well as outreach to doctors and other medical professionals. She joins Pfizer from Vertex Pharmaceuticals, where she was responsible for clinical and non-clinical development as well as both medical and regulatory.

Pfizer

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Scott Gottlieb, M.D.

Age: 51 years

Partner, New Enterprise Associates, Inc.'s Healthcare Investment Team and Resident Fellow of the American Enterprise Institute since 2019. Served as the 23rd Commissioner of the FDA from 2017 to 2019. Prior to serving as Commissioner of the FDA, Dr. Gottlieb held several roles in the public and private sectors, including serving as a Venture Partner to New Enterprise Associates, Inc. from 2007 to 2017.

Director of Illumina, Inc. Director of Aetion, Inc. a private healthcare data technology company, and Tempus, a private technology company. Board Member of National Resilience, Inc. Scientific Advisory Board Member of CellCarta. Member of the National Academy of Medicine and a contributor to the financial news network CNBC.

ROBERT NELSEN & LUCIANA BORIO

Bob Nelsen

Nelsen and Borio have worked closely in the past. He previously told *Endpoints News* that he spent last spring in his Seattle home, talking on the phone with Borio about her work running pandemic preparedness on the NSC, and fuming with her about the dire state of American manufacturing. Those talks helped lead to the launch of Nelsen's $800 million biologics manufacturing startup Resilience.

Borio, who previously served as the FDA's acting chief scientist and as VP at that nonprofit investment firm In-Q-Tel, serves as a senior fellow for global health at the Council on Foreign Relations for about the last year. Borio did not respond to a request for comment on whether she would keep that role at the CFR. She also serves as a member of CEPI's scientific advisory committee, where she provides Covid-related guidance and work on the public-private partnership's $3.5 billion plan to reduce the threat of future pandemics and epidemics.

And she played a hand in President Biden's race to nominate an FDA commissioner, according to one former agency official

HTTPS://ARCHIVE.IS/VQK8G

BOTH ON THE COUNCIL FOR FOREIGN RELATIONS

BOTH MEMBERS OF ARCH VENTURES

BOTH PLAYED KEY ROLES IN THE "CREATION OF RESILIENCE"

During the saga around the first accelerated approval for Sarepta Therapeutics' DMD drug eteplirsen, Borio — then FDA's acting chief scientist — wrote to then-FDA commissioner Robert Califf with fears that current acting commissioner Jane Woodcock "chilled scientific debate within (the FDA Center for Drug Evaluation and Review) and reduced the level of participation by the review team during the f nal stages of the decision-making process."

A former senior FDA official said it was this dispute that led Woodcock to push Bo rio out of the FDA entirely, after Borio circulated an internal memo concerning Woodcock's role with Sarepta. This former official also said he thinks Borio, who was vetted but ultimately not nominated to lead FDA, might have a hand in icing Woodcock's failure to land a nomination, too.

OWS SPENT 1.5 BILLION ON MODERNA TO PROVIDE A C19 "VACCINE"

moderna

...BUT THE 10YR OLD COMPANY, THAT HAD NEVER PRODUCED ANY FDA APPROVED VACCINE BEFORE HAD TO OFFSHOOT THE PROJECT TO 2 COMPANIES

"NEW" US STARTUP, ESTABLISHED IN 2020

RESILIENCE®

Lonza

127 YEAR OLD SWISS COMPANY EST. 1897

- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. 1 2 3 4 5

Lonza Group AG was founded in 1897 in Gampel, Switzerland.

"SINGHVI WAS ...AND AN OPERATING PARTNER AT FLAGSHIP PIONEERING, WHICH PLAYED A MAJOR ROLE IN THE CREATION OF MODERNA"

Prior to Resilience, Singhvi was CEO of Novavax and an operating partner at Flagship Pioneering, which played a major role in the creation and rise of Moderna.

Resilience was co-founded by Biotech venture capitalist Robert Nelsen, who is known for listening "to science's earliest whispers, even when data are too early for just about anyone else."

Nelsen was one of the earliest investors in Illumina, a California-based gene-sequencing hardware and software giant that is believed to currently dominate the field of genomics.

As mentioned in a previous Unlimited Hangout investigation, Illumina is closely tied to the Defense Advanced Research Projects Agency (DARPA) equivalent of the Wellcome Trust known as Wellcome Leap, which is also focused on "futuristic" and transhumanist "medicines."

Nelsen is now chairman of National Resilience's board, which is a "Who's Who" of big players from the U.S. National Security State, Big Pharma and Pharma-related "philanthropy."

HTTPS://CHILDRENSHEALTHDEFENSE.ORG/DEFENDER/CIA-LINKED-MRNA-MODERNA-OMICRON-COVID-BOOSTER-SHOT/

CHILDREN'S HEALTH DEFENSE ET. WHITNEY WEBB

LUCIANA BORIO

Expert Bio

Luciana Borio is a senior fellow for global health at the Council on Foreign Relations (CFR). She also is a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies.

GOTTLIEB

Scott Gottlieb, MD
@ScottGottliebMD · **Follow**

Big congratulations to @llborio and to @rtnarch and the team at Arch Ventures. Dr. Borio is a great colleague and brings a deep record of skill and accomplishment at FDA and NSC to this new role; where she'll continue to advance innovation, science, and public health.

> **BioCentury** @BioCentury
> Luciana Borio (@llborio) joins Arch as venture partner, brings expertise, FDA, White House experience in biodefense and public health and will focus on manufacturing, clinical trials, novel therapies. Firm promotes Carol Suh to partner buff.ly/3zIRFWX

11:46 PM · Jul 23, 2021

62 **See the latest COVID-19 information on Twitter**

On November 9, 2020, U.S. president-elect Joe Biden named Borio to be one of the 13 members of his COVID-19 Advisory Board.[9]

activities for the Office of Preparedness and Response.[12] Before leaving her role as assistant commissioner of FDA, she approved a partnership in infectious disease research with the Bill & Melinda Gates Foundation.[13]

In 2020, Borio was appointed by the Council on Foreign Relations to serve on its Independent Task Force on Improving Pandemic Preparedness, co-chaired by Sylvia Mathews Burwell and Frances Townsend.[14]

Other activities [edit]

- Codagenix, Member of the Scientific Advisory Board[15]
- Goldman Sachs, Consultant[16]

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JAN 28 2020

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OPINION | COMMENTARY

Act Now to Prevent an American Epidemic

Quarantines, flu vaccines and other steps to take before the Wuhan virus becomes widespread.

By Luciana Borio and Scott Gottlieb

Jan. 28, 2020 6:48 pm ET

PRINT TEXT 105

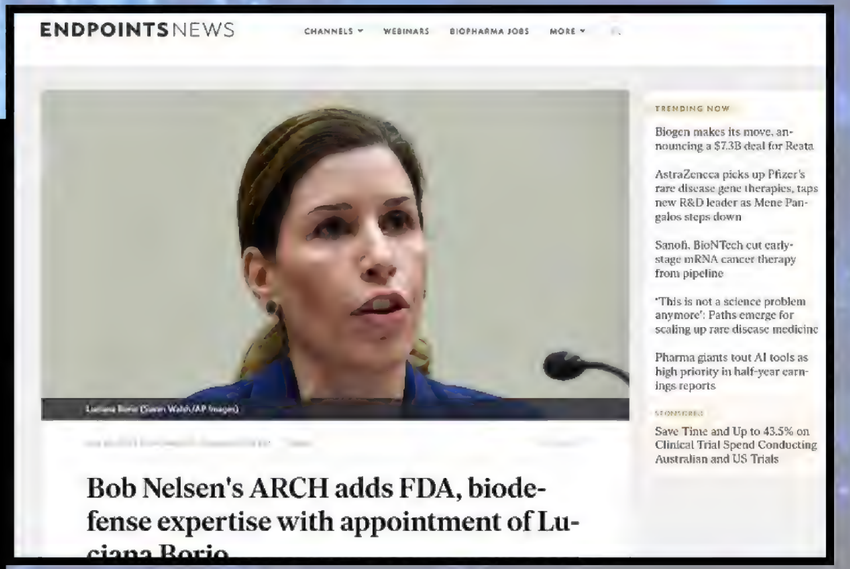
GOTTLIEB & LUCIANA BORIO

Gottlieb: There will be a rapid acceleration of coronavirus cases in US

192K views • 4 years ago

CNBC Television

Dr. Luciana Borio, vice president of In-Q-Tel and former Director of Medical and Biodefense Preparedness policy for the White ...



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RESILIENCE®

MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION

AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN

WHO MADE ROBERT NELSEN THE HEAD OF THE BOARD OF DIRECTORS

NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.

- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. [1] [2] [3] [4] [5]

BORIO IS ALSO A JOHNS HOPKINS GRAD, FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN

Palantir

OPERATION WARP SPEED

AUGUST 2019

Implications for outbreak management

Mike Ryan, MD, the WHO's executive director of emergency programs, told reporters that the WHO welcomes the results and he praised all of the Ebola workers, including the ones working on the infrastructure that allows doctors and nurses to deliver the treatments.

However, he said the tragedy is that not enough people are being treated and not enough people are coming to the hospital. "There are outstanding results for people who seek care early."

Earlier in the outbreak, an ethics committee in the DRC approved the four experimental treatments for compassionate use, and patients at all of the country's Ebola treatment centers have had access to them, along with safety monitoring. However, the formal clinical trial has been under way since November at four treatment centers with the help of the Alliance for International Medical Action (ALIMA), the International Medical Corps (IMC), and Doctors Without Borders (MSF).

At a media telebriefing today, Anthony Fauci, MD, director of the National institute of Allergy and Infectious Diseases (NIAID), said Regeneron was the drug that crossed the efficacy threshold, triggering a pause in the study. And he said the group recommended proceeding with mAb 114, because there were only small differences in the data between the two drugs.

He said the findings of the study are a "ringing endorsement" that ethical and scientifically sound research can be conducted in an outbreak setting.

Jean Jacques Meyumbe Tamfum, PhD, an Ebola expert who was recently appointed to head a group that is now leading the DRC's Ebola response, said he was grateful for the support of international partners, who are working in an extremely difficult setting. "We can no longer say that Ebola virus disease is not curable."

https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs

Richard Hatchett

1 language

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From Wikipedia, the free encyclopedia

(Redirected from Richard J. Hatchett)

Richard Hatchett is an American oncologist[1] and epidemiologist who has been serving as chief executive officer of the Coalition for Epidemic Preparedness Innovations (CEPI) in Oslo and London since 2017.[2][3] He was awarded the Secretary of Health and Human Services's Award for Distinguished Service.[4]

Early life and education [edit]

Hatchett grew up in Alabama.[5] He graduated from Vanderbilt University and Vanderbilt University School of Medicine.[6] He completed an internship and residency in Internal Medicine at New York Hospital – Cornell Medical Center, and a fellowship in Medical Oncology at the Duke University Hospital.[7] He was also a research associate at the National Heart & Lung Institute at Imperial College London and spent three months in northeast Gabon investigating three closely related Ebola outbreaks.[8]

Dr Richard J. Hatchett (2011)

Richard Hatchett:

Vanderbilt Univ,
Cornell, & Duke

Suspected Former CIA
Former BARDA
Current CEO at CEPI

Richard Hatchett:

Hatchett was the Chief Medical Officer and deputy director of the United States Biomedical Advanced Research and Development Authority (BARDA) from 2011 to 2016 before becoming the organization's acting Director in 2016.[20] At BARDA, he oversaw programs to develop medical countermeasures against chemical, biological, radiological and nuclear threats, pandemic influenza, and emerging infectious diseases and led or helped lead the development of vaccines, therapeutics and diagnostics for a number of emerging viruses, including the H3N2v and H7N9 influenza viruses, MERS, Ebola and Zika.[21]

CEO of CEPI, 2017–present [edit]

In 2017, Hatchett was appointed as CEO of the Coalition for Epidemic Preparedness Innovations, succeeding interim CEO John-Arne Røttingen.[22] In May 2020, amid the COVID-19 pandemic, he was appointed to the expert advisory group for the UK Government's Vaccine Task Force.[23] When the UK held the rotating presidency of the Group of Seven (G7) in 2021, the government also appointed him to serve as a member of the Pandemic Preparedness Partnership, chaired by Patrick Vallance.[24][25]

Under Hatchett's leadership, CEPI funded early development of COVID-19 candidate vaccines. CEPI also teamed up with the African Union to fund African vaccine production.[26][27] Together with Seth Berkley, he developed the concept for COVAX in early 2020.[28] CEPI is organizing a 2022 Covid summit.[29][30]

In March 2020, Hatchett warned about COVID-19.[31] He does not think Intellectual property rights significantly contribute to vaccine shortages.[32][33] He is concerned about supply chain problems,[34][35] and export controls.[36]

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
BARDA

COVAX

CEPI

DARPA

BILL & MELINDA GATES foundation

Leadership

Scientific Advisory Committee

William H. Gates Sr.

Warren Buffett

WATTENDORF JOINED DARPA IN 2010
HE WAS A LEAD PROGENITOR OF THE MONOCLONAL ANTIBODY PROGRAMS AT DARPA

HE NOW WORKS FOR THE BILL AND MELINDA GATES FOUNDATION

Dan Wattendorf

Director, Innovative Technology Solutions

DR. JAMES CROWE

DARPA

VANDERBILT

Dr. Crowe's lab delivered an antibody treatment to drugmaker AstraZeneca in a record 25 days. Others funded by the government's pandemic response program also shattered Matt Hepburn's 60-day mark, including biotech company AbCellera, working with Eli Lilly and Regeneron, which was used to treat President Trump.

Dr. James Crowe: This is the new normal. It's gonna be 60 days from here on out.

Well not quite yet - currently, antibodies are grown in a bioreactor like one at this Defense Department Rapid Response Plant in Florida. It'll take three weeks for this to produce 7,500 doses.

Dr. James Crowe: And so-- a lot of scientists are trying to figure out, can this be done faster?

Dr. Crowe has successfully tested a faster way: RNA, the genetic tool DARPA helped pioneer that was used to make the coronavirus vaccine in record time. In the next outbreak -- RNA would allow factories like this to churn out millions of doses a day.

https://www.cbsnews.com/news/last-pandemic-science-military-60-minutes-2021-04-11/

c&en

RIDGEBACK BI

A small-molecule antiviral discovered by Emory U could soon start human testing against COVID-19, the respirato the novel coronavirus. That's the plan of Ridgeback Biot censed the compound, EIDD-2801, from an Emory nonprofit

EMOR UNIVERSI

EIDD-2801 works similarly to **Gilead Sciences' remdesivir**, an unapproved drug that was developed for the Ebola virus and is ials against COVID-19. Both molecules are nucleoside analogs t m that blocks RNA polymerase, an essential component of viral rep

GILEAD

But remdesivir can only be given intravenously, meaning it would be difficult to deploy wid contrast, EIDD-2801 can be taken in pill form, says Mark Denison, a coronavirus expert a of the infectious diseases division at Vanderbilt Medical School. Denison partner researchers at the University of North Carolina to test the compound against coro

VANDERBILT

EIDD-2801 has other promising features. Many **antivirals work** by introducing errors into th genome, but, unlike other viruses, coronaviruses can fix some mistakes. In lab experiments,

https://cen.acs.org/biological-chemistry/infectious-disease/Emory-discovered-antiviral-poised-COVID/98/i12

Gilead Sciences and supporting researchers and clinicians are working with health authorities from the World Health Organization and in China to establish a placebo-controlled study to determine whether remdesivir is safe and effective in treating 2019-nCoV.

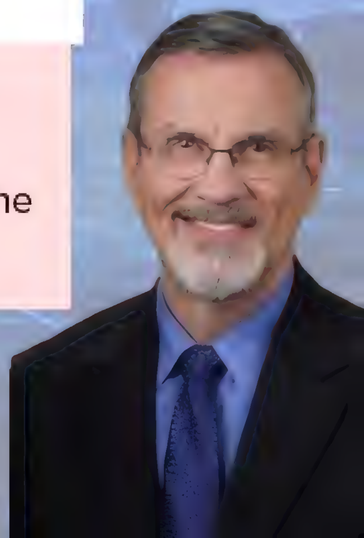
> "This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances."
>
> – Richard Whitley, M.D., UAB Distinguished Professor

"The collaboration between UAB, our colleagues at Southern Research, Vanderbilt University and the University of North Carolina, along with our pharmaceutical partner Gilead Sciences, is indicative of our collaborative approach to respond to outbreaks in real time, and in helping communities worldwide fight 2019-nCoV. This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances," Whitley continued.

Whitley expressed that the potential for mutation of 2019-nCoV means that UAB's AD3C and partners will need to build backup molecules for potential testing and treatment in the near future.

Get the latest COVID-19 information at uab.edu/coronavirus.

UAB is the lead institution for AD3C and research conducted; but the team unifies scientists experienced in virology, viral immunology, pathogenesis, medicinal chemistry and translation to human disease from UAB, University of North Carolina, Vanderbilt University, Emory University, Washington University, The University of Texas Medical Branch, Southern Research, the Emory Institute of Drug Discovery, the University of Colorado, Denver, and Oregon Health & Science University.



HTTPS://WWW.UAB.EDU/NEWS/HEALTH/ITEM/11082-INVESTIGATIONAL-COMPOUND-REMDESIVIR-DEVELOPED-BY-UAB-AND-NIH-RESEARCHERS-BEING-USED-FOR-TREATMENT-OF-NOVEL-CORONAVIRUS

Elsevier

Med (N Y). 2022 Mar 11; 3(3): 188–203.e4. Published online 2022 Feb 3. doi: 10.1016/j.medj.2022.01.004

PMCID: PMC8810411 | PMID: 35132398

A combination of two human neutralizing antibodies prevents SARS-CoV-2 infection in cynomolgus macaques

Ronald R. Cobb,[1,15] Joseph Nkolola,[2,15] Pavlo Gilchuk,[3,15] Abishek Chandrashekar,[2] Jingyou Yu,[2] Robert V. House,[4] Christopher G. Earnhart,[5] Nicole M. Dorsey,[5] Svetlana A. Hopkins,[6] Doris M. Snow,[4] Rita E. Chen,[7,8] Laura A. VanBlargan,[7] Manuel Hechenblaickner,[1] Brian Hoppe,[1] Laura Collins,[1] Milan T. Tomic,[9] Genevieve H. Nonet,[9] Kyal Hackett,[4] James C. Slaughter,[10] Mark G. Lewis,[11] Hanne Andersen,[11] Anthony Cook,[11] Michael S. Diamond,[7,8,12] Robert H. Carnahan,[3,13] Dan H. Barouch,[2,*] and James E. Crowe, Jr.[3,13,14,16,**]

-2022-

Dr. James Crowe [Vanderbilt] + the JPEO-CBRND & Ology Bioservices

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Kyal Hackett,[4] James C. Slaughter,[10] Mark G. Lewis,[11] Hanne Andersen,[11] Anthony Cook,[11] Michael S. Diamond,[7,8,12] Robert H. Carnahan,[3,13] Dan H. Barouch,[2,*] and James E. Crowe, Jr.[3,13,14,16,**]

[1]Ology Bioservices, Process Development and Manufacturing, Alachua, FL 32615, USA
[2]Center for Virology and Vaccine Research, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA 02215, USA
[3]Vanderbilt Vaccine Center, Vanderbilt University Medical Center, Nashville, TN 37232, USA
[4]Ology Bioservices, Frederick, MD 21701, USA
[5]Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, US Department of Defense, Frederick, MD 21703, USA
[6]Logistics Management Institute (LMI), Tysons, VA 22102, USA
[7]Department of Medicine, Washington University School of Medicine, St. Louis, MO 63110, USA
[8]Department of Pathology & Immunology, Washington University School of Medicine, St. Louis, MO 63110, USA
[9]Research and Development, Ology Bioservices, Inc., Alameda 94501, CA, USA
[10]Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN 37232, USA
[11]Bioqual, Inc., Rockville, MD 20850, USA
[12]Department of Molecular Microbiology, Washington University School of Medicine, St. Louis, MO 63110, USA
[13]Department of Pediatrics, Vanderbilt University Medical Center, Nashville, TN 37232, USA
[14]Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, TN 37232, USA
*Corresponding author

Contract ID:	HHSO100201300018I	Reference IDV:	-
Modification Number:	P00008	Transaction Number:	-
Award/IDV Type:	IDC Indefinite Delivery Contract	Action Obligation ($):	$0.00
Date Signed:	Nov 15, 2021	Solicitation Date:	-
Contracting Agency ID:	7505	Contracting Agency:	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	PSC Type:	P
PSC:	6505	PSC Description:	DRUGS AND BIOLOGICALS
NAICS:	325414	NAICS Description:	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	Entity State:	FL
Entity ZIP Code:	326158726	Additional Reporting Code:	-
Additional Reporting Description:	-	Unique Entity ID:	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS INC.
Legal Business Name:	OLOGY BIOSERVICES, INC.	CAGE Code:	3GQS9

Contract ID:	HHSO10033004T	Reference IDV:	HHSO100201300018I
Modification Number:	8	Transaction Number:	0
Award/IDV Type:	DO Delivery Order	Action Obligation ($):	$0.00
Date Signed:	May 18, 2018	Solicitation Date:	-
Contracting Agency ID:	7505	Contracting Agency:	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	PSC Type:	P
PSC:	6505	PSC Description:	DRUGS AND BIOLOGICALS
NAICS:	325414	NAICS Description:	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	Entity State:	FL
Entity ZIP Code:	326158726	Additional Reporting Code:	-
Additional Reporting Description:	-	Unique Entity ID:	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS INC.
Legal Business Name:	OLOGY BIOSERVICES, INC.	CAGE Code:	3GQS9

Ology Bioservices /Resilience +BARDA + ASPR 2018-2021 Contracts

https://www.fpds.gov/ezsearch/fpdsportal?s=ICD&indexName=awardfull&templateName=PDF&q=UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+INC.%22+UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+IN

Supaporn's research on bats has made her a giant in the field of virus discovery worldwide. She's caught the attention — and funding — of the US government, which funded her research through the US Agency for International Development or USAID and even through the Defense Advanced Research Projects Agency or DARPA, the Department of Defense's research arm.

"I work with some of the global leaders on virologic expeditions and I consider Chu at the very top of my list," said Dr. Michael Callahan, a US government clinical infectious disease specialist and the founder of DARPA's Prophecy program, which monitors and predicts virus evolution around the globe in order to prevent and contain outbreaks before they become pandemics.

Without her tireless work ethic and ability to navigate the needs of different governments and the worldwide scientific community, Callahan said, the US government would not have been able to work in Thailand on critically important global virology projects.

HEADS OF OWS:

MONCEF SLAOUI

MATTHEW HEPBURN [DARPA]

The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

Developing Safe and Effective Covid Vaccines — Operation Warp Speed's Strategy and Approach

Authors: Moncef Slaoui, Ph.D., and Matthew Hepburn, M.D. Author Info & Affiliations

Published August 26, 2020 | N Engl J Med 2020;383:1701-1703
DOI: 10.1056/NEJMp2027405 | VOL. 383 NO. 18

HEPBURN LEAD THE ADEPT PROGRAM
SLAOUI WAS ON THE BOARD FOR GSK,
& JOINED MODERNA'S BOARD OF
DIRECTORS IN 2017

Moncef Slaoui

Slaoui with GlaxoSmithKline CEO Emma Walmsley (December 2016)

Corporate directorships [edit]

In July 2017, he joined Moderna's Board of Directors.[29]

HTTPS://WWW.NEJM.ORG/DOI/10.1056/NEJMP2027405

AMERICAN Affairs

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Summer 2021 / Volume V, Number 2

Inside Operation Warp Speed: A New Model for Industrial Policy

by David Adler

Operation Warp Speed[1] (OWS) was launched on May 15, 2020. A partnership between the Departments of Health and Human Services (HHS) and Defense (DoD), other agencies, and the private sector, its goal was to "accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics to counter Covid-19." As a result of OWS, millions of lives were saved from the pandemic.

HTTPS://ARCHIVE.IS/L3NIV

OWS and Vaccine Development

Slaoui and Hepburn published an article in the *New England Journal of Medicine* in October 2020 in which they explained OWS's strategy for vaccine development: "We sought to build a diverse project portfolio that includes two vaccine candidates based on each of the four platform technologies."[9] Core to OWS's acceleration strategy was to run vaccine development processes in parallel rather than sequentially. Almost from the outset, OWS took on the unprecedented financial risk of funding and scaling up manufacturing efforts while the vaccine candidates were still in clinical trials.

To choose from over a hundred vaccine candidates, OWS used "down select," according to Hepburn, meaning whittling down the list using objective criteria. "The goal was never to try to pick one type of vaccine technology, let alone one company, but instead to keep the portfolio diverse. This was very deliberate given the many unknowns," he says. Vaccine candidates had to use one of the three platform technologies deemed most promising. They were further selected on the basis of clinical trial data and other formalized criteria, including their potential for scalability in manufacturing. In the end, three vaccine platforms, and two companies per platform, were targeted: (1) mRNA: Moderna, Pfizer/BioNTech; (2) replication-defective live-vector platform: AstraZeneca, Janssen; (3) recombinant-subunit-adjuvanted protein: Novavax, Sanofi/GSK.

OWS heavily invested in R&D for these vaccine candidates. Pfizer was an outlier in that OWS did not fund development or manufacturing, but it did place a roughly a $2 billion order for a hundred million doses, contingent upon FDA approval or authorization of the vaccine. Pfizer's CEO said the reason for this structuring was to "liberate" the company from government bureaucracy. Another unstated but possible motive was to immunize Pfizer's intellectual property from public claims related to federally funded research. Notably, moreover, Pfizer's partner BioNTech received $445 million in funding for development and scale-up manufacturing from the German government.[12]

Moderna designed its vaccine in just two days, demonstrating the power of mRNA technology. It produced an actual vaccine that could be tested on humans in sixty-three days. Nevertheless, Moderna, unlike Pfizer, lacked deep expertise at running clinical trials, and faced the problem of too few minority volunteers. Here the NIH stepped in to help. OWS pursued a strategy of running clinical trials concurrently rather than sequentially, saving significant time.

HTTPS://ARCHIVE.IS/L3NIV

Dr. Michael Callahan, an infectious disease specialist at Massachusetts General Hospital and Harvard Medical School, explains just how radical these results were, including the novel technology and development efforts that led to them: "mRNA-based protein expression is the most recent interesting American invention," Callahan says. "Warp Speed could not have happened if the technology had not been developed to move this quickly. We got very lucky with mRNA." With mRNA, scientists only need to know the sequence of the virus to design a vaccine. Sequence data was provided by the Chinese in the first week of January 2020. China's capabilities in this area are comparable to or better than America's.

Callahan's academic bio doesn't convey the depth of his expertise. Callahan previously oversaw DARPA's biodefense therapeutics portfolio, the "Accelerated Manufacture of Pharmaceuticals" (AMP) program, whose goal was to radically accelerate the manufacturing of protein vaccines, and sister programs "7 Day Biodefense" and "Prophecy" (to predict virus evolution). Callahan coled the world's largest international medical evacuation from a hot zone, the repatriation of nearly four hundred Americans from the Covid-19-plagued *Diamond Princess* cruise ship, and emergency care of infected passengers on the *Grand Princess* cruise. He was then recruited as special adviser on Covid-19 to the assistant secretary of preparedness and response (ASPR), Robert Kadlec.

But there are potential risks, even controversies, related to OTs. They bring reduced transparency, and some exemptions from regulations designed to protect taxpayers. Specifically, the concern around OWS is that OTs might have allowed pharma companies to circumvent the Bayh-Dole Act,[17] which provides the public with rights in intellectual property arising out of federally funded research, including march-in rights.[18]

EUA. Emergency Use Authorization (EUA) is a mechanism to allow use of medical products without full FDA approval during a health emergency, such as a pandemic. Traditional FDA approval for a vaccine can take years, whereas an EUA is much quicker, though it still involves rigorous evaluation by the FDA. As the FDA notes, "efforts to speed vaccine development to address the ongoing Covid-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety."[19]

The GAO, however, was slightly critical in its report assessing the use of EUAs during the pandemic. Its study in no way argued that the authorized medicines weren't safe, but rather that "the FDA does not uniformly disclose its scientific review of safety and effectiveness data for EUAs," as it does for traditional approvals.[20]

HTTPS://ARCHIVE.IS/L3NIV

Someone still had to make hundreds of millions of doses of mRNA, however, and very few companies had this expertise. Moderna already operated an existing advanced biotech manufacturing facility, but more production capacity was required. Moderna partnered with the contract manufacturer Lonza in May 2020,[27] long before its vaccine received an EUA. With funding provided by OWS through BARDA, the companies established mRNA manufacturing lines at Lonza's factories in the United States and Switzerland.

Admiral Brett P. Giroir, MD, assistant secretary of HHS, took on the role of coordinating Covid-19 diagnostic testing in March 2020. He explains some of the challenges facing the United States: "We didn't have a stockpile of tests or basic materials, and very little domestic manufacturing capacity. We had to scramble to import basic materials like swabs and pipette tips while we jump-started domestic production. There were no rapid tests, only PCR tests that required sophisticated laboratories." Admiral Giroir began flying in one 747 a week filled just with swabs and similar basic materials from Europe.

Admiral Giroir, who earlier had directed the Defense Sciences Office at DARPA, implemented private-public partnerships to scale the manufacturing of tests. The government invested billions of dollars to build domestic test manufacturing capacity. By June 2020, the United States was testing five hundred thousand people daily.

In terms of vaccine production, OWS had been working with companies to scale up manufacturing almost from inception, when vaccine candidates were still only in preclinical trials. Slaoui and Hepburn, in their *NEJM* article, described some of the ways OWS offered technical support for the rapid scaling of manufacturing:

> To ensure that industrial processes are set, running, and validated for FDA inspection when phase 3 trials end, OWS is supporting facility building or refurbishing, equipment fitting, staff hiring and training, raw-material sourcing, technology transfer and validation, bulk product processing into vials, and acquisition of ample vials, syringes, and needles for each vaccine candidate.[26]

Previous DARPA investments are also showing promise in combating COVID-19. For example, in 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.

These DARPA programs are part of a broader biodefense effort to address threats that include naturally occurring epidemics, as well as accidental biological exposures, biowarfare, and bioterrorism. The nation's biodefense enterprise is distributed, spanning multiple departments and agencies with different missions, making preparing for and responding to a diverse and evolving set of biological threats challenging. In 2016, Congress directed the Secretaries of Health and Human Services (HHS), Defense, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and associated implementation plan (P.L. 114-328, Section 1086). Issued in September 2018, the *National Biodefense Strategy* (with an implementation plan in Annex I) calls for the integration of biodefense R&D into federal planning, emphasizing the development of procedures and policies for interagency coordination of R&D efforts associated with responding to a biological incident. While the plan also calls for the sustainment of a robust national science and technology base to support biodefense, it does not articulate a need for interagency R&D planning and coordination. In 2015, the Blue Ribbon Study Panel on Biodefense, now the Bipartisan Commission on Biodefense, highlighted military-civilian collaboration in biological R&D as one of many issues that "deserve more congressional oversight."

The Biological Technologies Office currently supports a number of programs that address pandemics. Since the emergence of COVID-19, DARPA has shifted the efforts of many of these programs to focus specifically on the coronavirus pandemic. According to DARPA,

> There is currently a mismatch between the rapidity at which biological threats can emerge and proliferate and the response time for developing and deploying effective medical countermeasures.… Cognizant of the need for speed, DARPA began aggressively pursuing medical countermeasures research more than a decade ago with a focus on developing generalizable, virus-agnostic technologies that can address whatever threat emerges, rather than building a collection of one-off solutions.

Examples of current DARPA investments include the Pandemic Prevention Platform (P3) program, whose goal is to develop methods "capable of producing relevant numbers of doses against any known or previously unknown infectious threat within 60 days of identification of such a threat." Awardees of the P3 program have been applying the results of their work to COVID-19. For example, a COVID-19 antibody treatment developed with support from DARPA by AbCellera Biologics, in partnership with Eli Lilly and the National Institutes of Health (NIH) Vaccine Research Center, began human clinical trials in June 2020.

Additionally, an awardee from DARPA's Epigenetic Characterization and Observation (ECHO) program, Fluidigm, in collaboration with a consortium of medical schools, is developing an early detection test for SARS-CoV-2, the novel virus that causes COVID-19.

In its role as advisor to the Secretary of HHS, the National Biodefense Science Board (NBSB), stated that

> R&D for technologies, platforms, and systems to develop new MCM [medical countermeasures] against Disease X in 28 days from the recognition of the outbreak, which NBSB recommends as [a]

https://sgp.fas.org/crs/natsec/IN11446.pdf

Congressional Research Service
Informing the legislative debate since 1914

INSIGHT

DARPA's Pandemic-Related Programs

June 30, 2020

The Defense Advanced Research Projects Agency (DARPA) has contributed to the development of important military and commercial technologies, including stealth and personal electronics. DARPA's role and investments in defense-related research and development (R&D), including biological defense, has potential significance for the science and technology available to address the Coronavirus Disease 2019 (COVID-19) pandemic and any future biological threats. Advances in genome sequencing and editing, along with the application of engineering principles and computing and information sciences to the field of biology, have created opportunities to accelerate and expand the development of biotechnology products and processes. Although DARPA has invested in biological research since its establishment in 1958, in 2014 the agency created the Biological Technologies Office, which focuses specifically on the biological sciences and biotechnology.

Nathan Wolfe

3 languages

Article Talk | Read Edit View history Tools

From Wikipedia, the free encyclopedia

Nathan Daniel Wolfe (born 24 August 1970) is an American virologist. He was the founder (in 2007) and director of Global Viral[1] and the Lorry I. Lokey Visiting Professor in Human Biology at Stanford University.

Career [edit]

Wolfe spent over eight years conducting biomedical research in both sub-Saharan Africa and Southeast Asia. He is also the founder of Metabiota, which offers both governmental and corporate services for biological threat evaluation and management. He serves on the editorial board of *EcoHealth* and *Scientific American* and is a member of DARPA's Defense Science Research Council. His laboratory was among the first to discover and describe the Simian foamy virus.[2]

In 2008, he warned that the world was not ready for a pandemic.[3]

In 2011, his book *The Viral Storm: The Dawn of a New Pandemic Age*[4] was short-listed for the Winton Prize.[5]

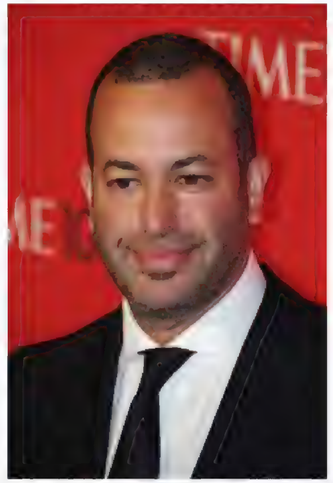
As reported in a *Wired* feature in 2020, Wolfe worked with the German insurance firm Munich Re to offer major corporate leaders pandemic policies, which were not purchased; a stark reality during the ensuing COVID-19 pandemic.[6]

Awards [edit]

Wolfe has been awarded more than $40 million in funding from a diverse array of sources including the U.S. Department of Defense, Google.org, the National Institutes of Health, the Skoll Foundation, the Bill & Melinda Gates Foundation and the National Geographic Society.[7]

- Fulbright fellowship recipient (1997)
- National Geographic Emerging Explorer (2004)[2]
- NIH Director's Pioneer Award (2005)
- *Popular Science*: "Brilliant 10" (2006)
- *Rolling Stone*: "Top 100 Agents of Change" (2009)
- World Economic Forum's Young Global Leaders (2010)

Nathan D. Wolfe



Wolfe in 2011

Born	August 24, 1970 (age 53) Detroit, Michigan, U.S.
Citizenship	United States
Alma mater	Stanford, Harvard
Scientific career	
Fields	Virology
Institutions	Stanford, UCLA

NATHAN WOLFE

Ecohealth Alliance
Collaborator with
DARPA, DoD, Google, NIH, Skoll,& The Bill & Melinda Gates Foundation

Wolfe founded Metabiota; a company that is funded by In-Q-Tel [CIA] since 2017 and as of 2019 Metabiota was the 3rd largest contract for IQT.

In 2014 HunterBiden bought a 14% stake in the company.

Metabiota has ties to the Pentagon funded Biolabs in Ukraine.

Metabiota was also funded under USAID [CIA] alongside EcoHealth in the year leading up to the Pandemic

RIDGEBACKBIO

George Painter, PhD

George Painter, Ph.D., is a professor in the Department of Pharmacology and Chemical Biology at Emory University School of Medicine, CEO of the Drug Innovation Ventures at Emory (DRIVE), and director of the Emory Institute for Drug Development. Dr. Painter has decades of experience in the discovery and development of pharmaceutical agents for the biotechnology and global pharmaceutical sectors. Within three years of its start, DRIVE discovered and licensed an antiviral agent to a major pharmaceutical firm and secured two major federal antiviral drug development contracts. Over the last 30 years, he has played a major role in the discovery, development, and implementation of modern antiviral therapy.

Before coming to Emory in 2012, Dr. Painter cofounded and led the biotechnology firm Chimerix, Inc. During his tenure there, he led the development of a drug for the prevention and treatment of adenovirus infection in stem cell transplant patients, a previously untreatable and often fatal infection in children. Before Chimerix, he was a founding member of the management team of Triangle, Inc., where he led the development of the now widely used HIV drug, Emtriva. In 2002, Triangle was sold to Gilead Sciences.

EMORY UNIVERSITY

Prior to entering the biotech sector, Dr. Painter held senior management positions in large pharmaceutical companies including Burroughs Wellcome Co and what is now GlaxoSmithKline, where he led the discovery, development, and commercialization of antiviral agents to treat HIV and Hepatitis B. He holds more than 150 patents, many of which have led to approved, commercially available drugs or combinations of drugs for the treatment of HIV, Hepatitis B, smallpox, and coronavirus infections. He has published more than 120 peer-reviewed papers. Dr. Painter earned his BS in Chemistry, MS in Physical Organic Chemistry, and Ph.D. in Organic Chemistry at Emory. He was a post-doctoral fellow at the California Institute of Technology.

https://ridgebackbio.com/about/development-advisory-board/george-painter-phd/

ORGANIZATION

Triangle Pharmaceuticals

Summary | Financials | People | Technology

About

Triangle Pharmaceuticals focus on potential therapies for the human immunodeficiency virus (HIV), including AIDS, and the hepatitis B virus

Acquired by
Gilead Sciences

Durham, North Carolina, United States
101-250
Pre-Seed
Private
500,868

Highlights

Investors
2

Similar Companies
3

Industries
Biotechnology | Health Care | Medical

Founded Date
1995

Operating Status
Active

Headquarters Regions
Research Triangle, East Coast, Southern US

Founders
Karl Hostetler

Last Funding Type
Pre-Seed

https://www.crunchbase.com/organization/triangle-pharmaceuticals

By READDI, May 20th, 2022 – The National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, awarded the UNC Gillings School of Global Public Health and the UNC Eshelman School of Pharmacy a $65 million grant, establishing an Antiviral Drug Discovery Center to develop oral antivirals that can combat pandemic-level viruses like COVID-19.

The center builds upon and is tightly affiliated with Carolina's Rapidly Emerging Antiviral Drug Development Initiative, or READDI.

The READDI-AViDD Center (READDI-AC), one of nine established by the NIH, is an integrated public-private partnership with a renowned, interdisciplinary research team of experts from the Gillings and Eshelman schools, as well as UNC School of Medicine. They will apply cutting-edge technologies to develop oral therapies that target viral families with high potential to cause a pandemic in the future.

READDI was initially founded and supported through Carolina's Creativity Hubs initiative and the Eshelman Institute for Innovation. Recent funding from the North Carolina General Assembly and support from several members of the North Carolina Congressional delegation have been critical in aiding the team's work. By drawing on expertise and technology from academic and industry partners, including Janssen Pharmaceuticals, Takeda, Chimerix Inc. and Pardes Biosciences, READDI-AC will aid in the discovery and development of broad-spectrum antivirals that reduce the risk of severe illness and death from these highly contagious viruses.

“The devastating effects of the SARS-CoV-2 pandemic illustrates the critical need for new antiviral treatments for both existing and future viral disease threats,” said Mark Heise, professor of genetics at the School of Medicine and co-founder of READDI alongside Baric and Associate Professor of Microbiology and Immunology Nathaniel Moorman. “The READDI-AC Program is poised to significantly enhance our ability to treat existing threats while preparing for future viral disease outbreaks.”

The READDI-AC’s consortium of international collaborators also includes the University of Toronto, Diamond Light Source LTD, Sichting VU, Duke University, McGill University, Rutgers University, the University of Alberta, the University of Wisconsin-Madison, University College London, Vanderbilt University and Vanderbilt University Medical Center, the University of Pennsylvania, the University of Maryland-Baltimore County, Oregon Health and Science University, Janssen Pharmaceutica NV, the University of Colorado-Denver, and the University of Tennessee Health Science Center.

Research reported in this publication was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number U19AI171292. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

https://readdi.org/stories/readdi-receives-65m-grant-from-nih-to-establish-an-antiviral-drug-discovery-avidd-center/

EBANGA™

Ridgeback would like to acknowledge and thank our collaborators on the EBANGA™ (ansuvimab-zykl, mAb114) development program:

BARDA

National Institute of Allergy and Infectious Diseases

National Institutes of Health
Turning Discovery Into Health

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Frederick National Laboratory for Cancer Research
sponsored by the National Cancer Institute

World Health Organization

ALIMA

MEDECINS SANS FRONTIERES

International Medical Corps

Samaritan's Purse
INTERNATIONAL RELIEF

Lagevrio (molnupiravir)

Ridgeback would like to acknowledge and thank our collaborators on the Lagevrio (molnupiravir; EIDD-2801) development program:

EMORY UNIVERSITY

DRIVE
INFECTIOUS INNOVATION

MERCK

agile
Coronavirus Drug Testing Initiative

https://ridgebackbio.com/about/collaborations/

Press Release

Chimerix and BARDA Announce Contract Extension of $13.0 Million for the Continued Development of Brincidofovir for Smallpox

Chimerix and BARDA Announce Contract Extension of $13.0 Million for the Continued Development of Brincidofovir for Smallpox

DURHAM, N.C., Sept. 14, 2015 (GLOBE NEWSWIRE) – Chimerix, Inc. (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced an extension of its contract with the Biomedical Advanced Research and Development Authority (BARDA) for the development of the broad spectrum antiviral, brincidofovir, as a medical countermeasure to treat smallpox.

This latest contract extension provides an additional $13.0 million to Chimerix for a period of 15 months. The company received an initial award from BARDA in February 2011 to support early research and development of brincidofovir in animal models of smallpox (Contract Number HHSO100201100013C) and received a contract extension of $17.0 million in September 2014.

https://ir.chimerix.com/news-releases/news-release-details/chimerix-and-barda-announce-contract-extension-130-million

BIOPHARMA, PHARMA

To focus on cancer, Chimerix sells rights to antiviral drug that defined the biotech

Chimerix is selling global rights to smallpox drug Tembexa, the biotech's only FDA-approved product, as a way to fund clinical development of a therapy in pivotal testing for a rare type of brain cancer. The deal marks Chimerix's nearly complete departure from the antiviral work that defined the company for most of its history.

By Frank Vinluan on May 16, 2022

Chimerix's first approved drug had several high-profile setbacks and ended up with a much narrower regulatory nod than initially hoped. Now the company is selling rights to that drug to Emergent BioSolutions as a way of raising cash as it looks ahead to a key late-stage trial for its lead asset, a drug that treats a rare type of cancer.

https://medcitynews.com/2022/05/to-focus-on-cancer-chimerix-sells-rights-to-antiviral-drug-that-defined-the-biotech/

Tembexa, the drug that Emergent is getting, was approved last June as a treatment for smallpox infection. Under a partnership with Biomedical Advanced Research and Development Authority (BARDA), Chimerix developed the antiviral as a medical countermeasure to protect against smallpox used as a biological weapon. For that application, the drug's customer base is essentially a single customer—BARDA. So far, Durham, North Carolina-based Chimerix has yet to record sales of the approved drug to the agency.

According to terms of the deal announced Monday, Emergent has agreed to pay Chimerix $225 million when the deal closes, plus up to $100 million more in up to four $25 million milestone payments. Each of those milestone payments is tied to BARDA exercising procurement options on Tembexa. Chimerix said that it is in negotiations with BARDA on a procurement contract and will continue to lead that process until complete.

https://medcitynews.com/2022/05/to-focus-on-cancer-chimerix-sells-rights-to-antiviral-drug-that-defined-the-biotech/

Had things worked out differently, Tembexa might have found wider use as a broad-spectrum antiviral. The drug, known for most of its history under the name brincidofovir, was hoped to offer advantages over an injectable Gilead Sciences antiviral, cidofovir. In addition to its pill formulation that is easier for patients to take, Chimerix had hoped brincidofovir would be safer than the Gilead drug, which is associated with kidney damage. The first indication Chimerix targeted was treating cytomegalovirus infections in transplant patients.

In 2009, during the early days of brincidofovir's clinical development, Chimerix also began making the drug available under the FDA's compassionate use program, which allows access to experimental therapies for patients who have no therapeutic options. As the antiviral progressed in clinical trials, Chimerix closed its compassionate use program to focus on pivotal tests of the drug that could support an application seeking FDA approval. But in 2014, Chimerix found itself in the midst of a national debate about the "right to try" experimental drugs. A Virginia boy, Josh Hardy, was suffering from adenovirus infection following cancer treatment and a bone marrow transplant. His physicians recommended treatment with brincidofovir under compassionate use. The debate about access to the still experimental drug played out prominently in national news and social media. The company's CEO even received death threats.

https://medcitynews.com/2022/05/to-focus-on-cancer-chimerix-sells-rights-to-antiviral-drug-that-defined-the-biotech/

https://medcitynews.com/2022/05/to-focus-on-cancer-chimerix-sells-rights-to-antiviral-drug-that-defined-the-biotech/

In 2019, Chimerix outlicensed global rights to brincidofovir to SymBio Pharmaceuticals for development in all human indications, except for orthopoxviruses, such as smallpox. Tokyo-based SymBio paid $5 million up front and could pay up to $180 million more if the drug achieves regulatory and commercial milestones. The deal put Chimerix in line for royalties from sales if SymBio commercializes the drug. According to the deal terms with Emergent, Chimerix is eligible to receive up to $12.5 million in regulatory milestones stemming from SymBio's work with the drug.

CHIMERIX

ERIK J. STEMMY

- **NIH PRINCIPLE INVESTIGATOR**
- **VIRAL ARI) RESPIRATORY DISEASES BRANCH DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES, NIAID/NIH**

2023 Award Winner

Erik Stemmy

STEMMY

2023 Awards Summary

1

Group Award Won

NIAID (National Institute of Allergy and Infectious Diseases)

Scientific/Medical - Research

Group Awards

SARS-CoV-2 Assessment of Viral Evolution (SAVE) Program Group

In recognition of significant contributions to the real-time assessment of emerging SARS-CoV-2 mutations that could impact transmissibility, virulence, and susceptibility to infection or vaccine-induced immunity.

HTTPS://DIRECTORSAWARDS.HR.NIH.GOV/AWARDS/2023/WINNERS/S/SAFF04EFEF52FE037DC4438A43E0D567F/

STEMMY

Year	Occupation	Paygrade	Base Salary	Bonus	Location
2022	General Health Science	GS-14	$155,687	$0	Rockville, Maryland
2021	General Health Science	GS-14	$151,118	$0	Rockville, Maryland
2020	General Health Science	GS-14	$145,578	$0	Rockville, Maryland
2019	General Health Science	GS-14	$136,725	$0	Rockville, Maryland
2018	General Health Science	GS-14	$129,869	$0	Rockville, Maryland
2017	General Health Science	GS-14	$126,958	$0	Rockville, Maryland
2016	General Health Science	GS-14	$116,146	$0	Rockville, Maryland
2015	General Health Science	GS-14	$110,902	$0	Rockville, Maryland
2014	General Health Science	GS-13	$89,924	$0	Bethesda, Maryland

In 2022, Erik J. Stemmy was a General Health Scientist at the National Institutes of Health in Rockville, Maryland. Stemmy began working at the National Institutes of Health in 2011 with a starting salary of $62,467. Since then, Stemmy's salary has increased to $155,687 in 2022.

Erik J. Stemmy is a GS-14 under the general schedule payscale.

Erik J. Stemmy's 2022 pay is

↑ 36%

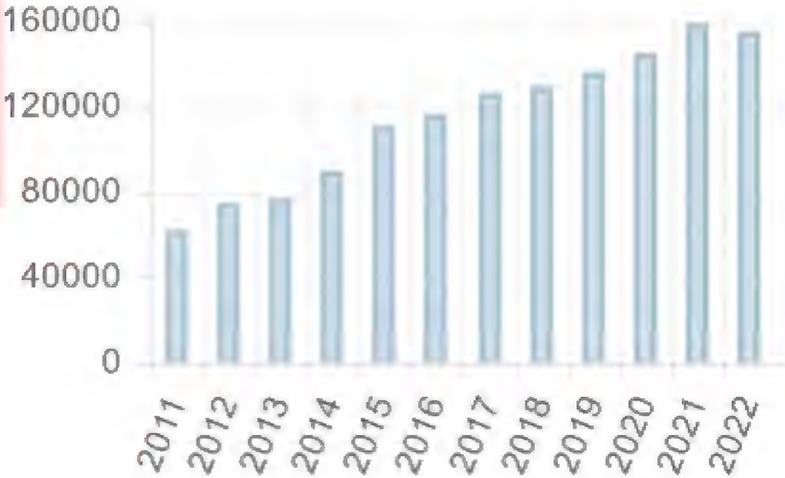
higher than the average General Health Scientist across all agencies.

Erik J. Stemmy's 2022 pay is

↑ 118%

higher than the average pay of a GS employee at the National Institutes of Health.

Erik J. Stemmy's pay trend during his or her government career in the National Institutes of Health:



STEMMY

https://www.federalpay.org/employees/national-institutes-of-health/stemmy-erik-j

STEMMY

The George Washington University
Ph.D., Immunology
2006 - 2011

Activities and societies: Institute for Biomedical Sciences

Dissertation topic: Characterizing the role of extracellular cyclophilins in chronic allergic asthma.

Georgetown University
M.S., Microbiology and Science Policy
2003 - 2005

Licenses & certifications

Certification for Contracting Officer's Representatives Level III (FAC-COR)
United States Federal Government
Issued Aug 2018

Experience

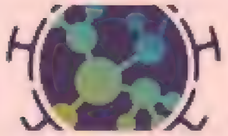
STEMMY

National Institute of Allergy and Infectious Diseases (NIAID)
Full-time · 13 yrs 2 mos

Team Lead
Sep 2022 - Present · 1 yr 8 mos
Hybrid

Team Lead managing NIAID's Centers of Excellence for Influenza Research and Response (CEIRR) Network, a global multi-disciplinary network focused on understanding influenza natura ...see more

Immunology, Research and +3 skills



CEIRR Network
NIAID-funded Centers of Excellence for Influenza Research and Response Network

Program Officer
Mar 2011 - Feb 2023 · 12 yrs

Program Officer in the Viral Respiratory Diseases Section of the Respiratory Diseases Branch in NIAID's Division of Microbiology and Infectious Diseases. I manage a diverse grant and contract research portfolio covering Rhinoviruses and Human Coronaviruses, including basic research, therapeutic & vaccine development, and pre/clinical testing. I also manage the Data Processing and Coordination Center for NIAID's Centers of Excellence for Influenza Research and Surveillance, a global network of researchers investigating influenza pathogenesis, transmission, and evolution.

https://grantome.com/search?q=erik+stemmy

STEMMY

69	2020
29	2021
29	2018
28	2019
25	2014
24	2015
22	2016
20	2017
18	2013
18	2012
8	2010

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Funder

Year

69	2020
29	2021
29	2018
28	2019
25	2014
24	2015
22	2016
20	2017

Search

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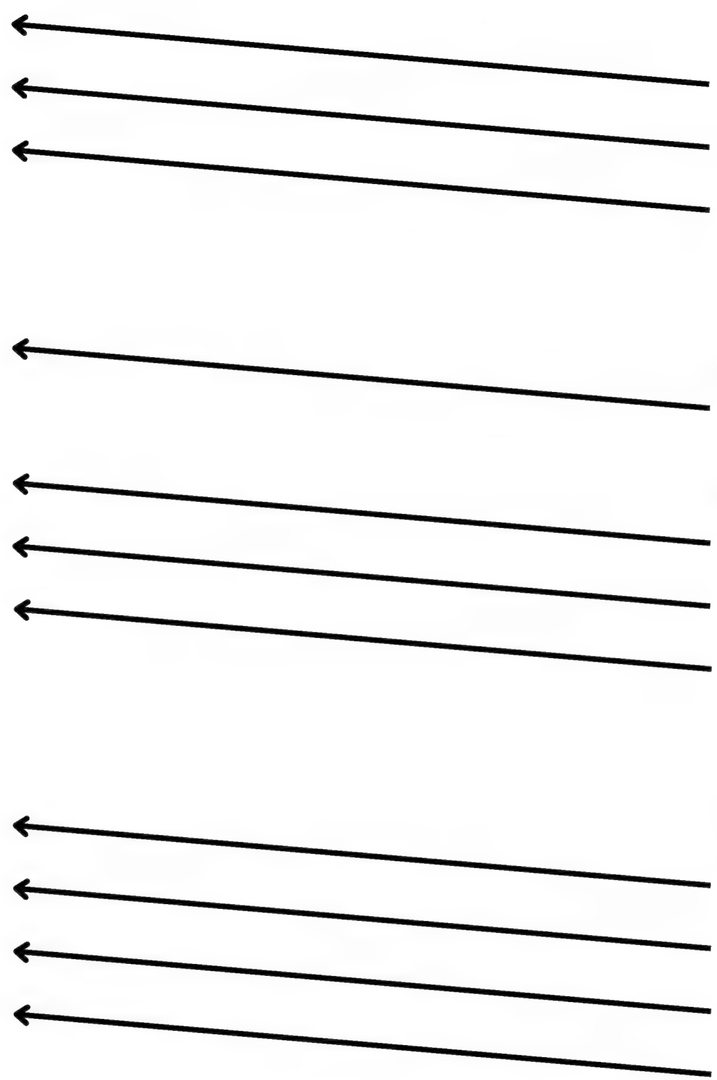
NIH 2021 R00 AI
Structural Studies of the Coronavirus Life Cycle
Kirchdoerfer, Robert Nicholas / University of Wisconsin Madison

NIH 2021 R01 AI
Rational design and evaluation of novel mRNA vaccines against MERS-CoV
Du, Lanying / New York Blood Center

NIH 2021 R21 AI
Accelerating discovery of neutralizing paratopes with Functional Antibody Screening Technology
De Figueiredo, Paul; Han, Arum / Texas A&M University

NIH 2021 R21 AI
Rhinovirus C Infection in Normal and Asthmatic Human Airway Epithelium at Single Cell Resolution
Scull, Margaret Adele; Rosenberg, Brad / University of Maryland College Park

☐	10	Denison, Mark R.
☐	22	Perlman, Stanley
☐	15	Li, Fang
☐	14	Makino, Shinji
☐	12	Du, Lanying
☐	9	Sheahan, Timothy ...
☐	9	Baker, Susan C.
☐	8	Frieman, Matthew ...
☐	8	Hotez, Peter J.
☐	7	Kirchdoerfer, Robe...
☐	5	Daniel, Susan
☐	7	Bottazzi, Maria Ele...
☐	6	Weiss, Susan R.
☐	6	Daszak, Peter
☐	5	McLellan, Jason Sc...
☐	5	Menachery, Vineet ...
☐	5	D'Souza, Victoria ...
☐	5	Harris, Eva
☐	5	Poehling, Katherin...
☐	4	Graepel, Kevin Whi...



Mark Denison < Vanderbilt

Stanley Perlman <Iowa

Li Fang < U Minn

Timothy Sheahan <UNC

Matthew Frieman <Johns Hopkins

Peter Hotez <UTMB

Robert Kirchdoerfer <UW Madison

Susan R. Weiss < UPENN, UCSF

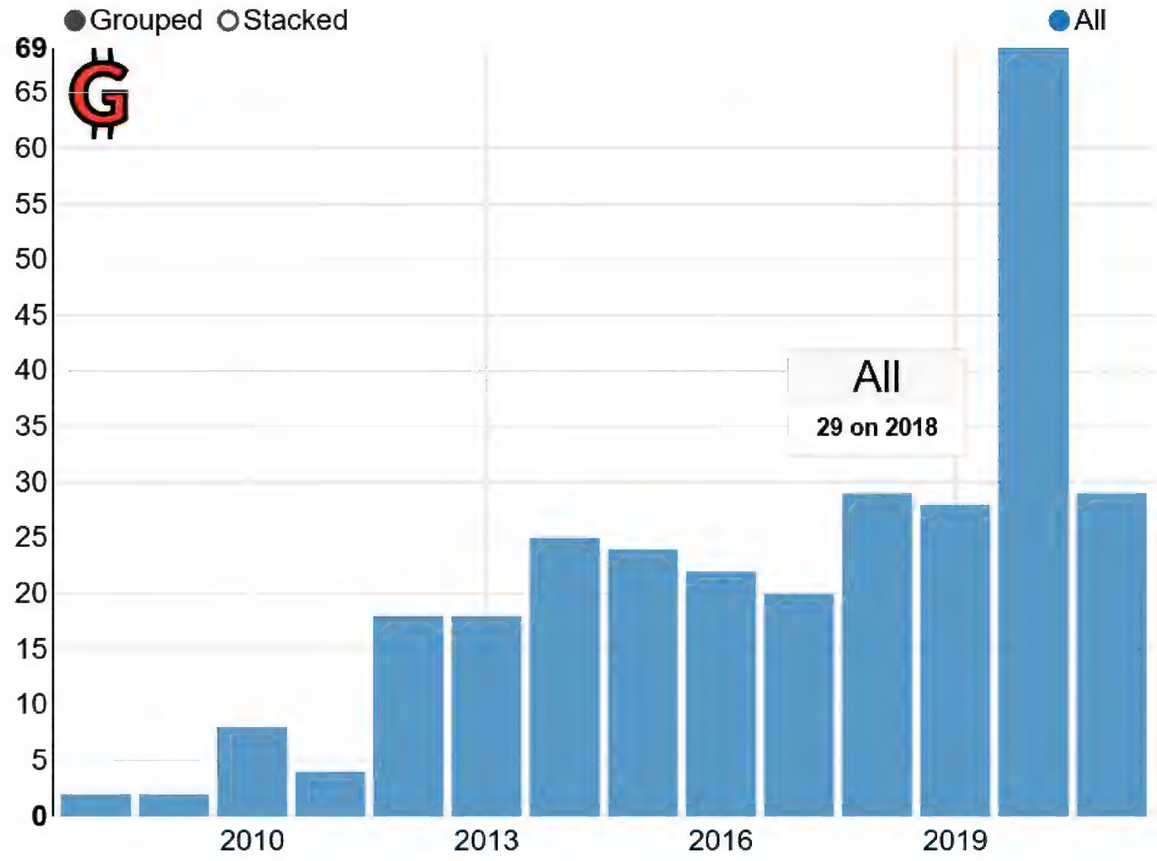
Peter Daszak <EHA

Jason S. McLellan <Johns Hopkins, VRC

Vineet Menachery < UTMB & UNC

Authors on grant projects under **Stemmy**

☐	24	University of Nort...
☐	20	University of Iowa
☐	19	Vanderbilt Univers...
☐	13	University of Maryl...
☐	12	New York Blood C...
☐	11	University of Penn...
☐	11	University of Texas...
☐	9	Baylor College of ...
☐	9	Loyola University ...
☐	8	University of Wisc...
☐	8	University of Minn...
☐	8	Harvard University
☐	7	University of Texas...
☐	7	Cornell University
☐	6	Ecohealth Alliance,...
☐	5	University of Maryl...
☐	5	University of Califo...
☐	5	Wake Forest Unive...
☐	4	Texas A&M Univer...
☐	4	University of Texas...
☐	4	Planet Biotechnolo...
☐	4	Johns Hopkins Uni...
☐	4	Wadsworth Center
☐	3	Colorado State Uni...
☐	3	University of Florida



Stemmy was program lead on 20-29 grants annually from 2013-2019, then suddenly in 2020 that jumped over double the usual to 69 grants

STEMMY

https://www.nature.com/articles/s41579-018-0118-9

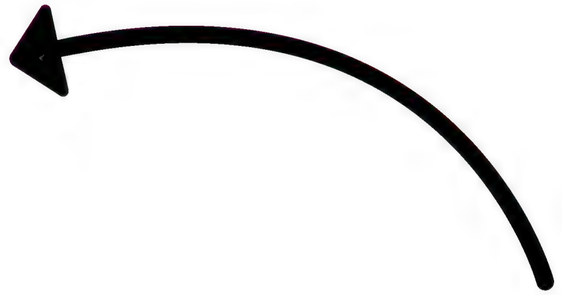
nature reviews microbiology

Review Article | Published: 10 December 2018

Origin and evolution of pathogenic coronaviruses

Jie Cui, Fang Li & Zheng-Li Shi ✉

Nature Reviews Microbiology **17**, 181–192 (2019) | Cite this article



Fang Li & the “bat Lady” Zheng-Li Shi
December 2018

Abstract

Severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are two highly transmissible and

- From: "David Morens" [redacted]@gmail.com>
  Sent: 7/13/2020 9:21:23 PM +0000
  To: "Keusch, Gerald T" [redacted]@bu.edu>
  CC: Peter Daszak [redacted]@ecohealthalliance.org>
  Subject: Re: PRO/AH/EDR> COVID-19 update (312): China, SARS-CoV2 origin, animal reservoir, WHO mission

- From: "David Morens" [redacted]@gmail.com>
  Sent: 4/26/2020 9:29:26 PM +0000
  To: "Keusch, Gerald T" [redacted]@bu.edu>
  CC: Peter Daszak [redacted]@ecohealthalliance.org>; Aleksei Chmura [redacted]@ecohealthalliance.org>
  Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Erik Stemmy was the Program Officer for AI110964

EcoHealth ALliance

Funding Agency

Agency	National Institute of Health (NIH)	Project Start	2014-06-01
Institute	National Institute of Allergy and Infectious Diseases (NIAID)	Project End	2020-04-24
		Budget Start	2019-07-24
Type	Research Project (R01)	Budget End	2020-04-24
Project #	2R01AI110964-06	Support Year	6
Application #	9819304	Fiscal Year	2019
Study Section	Clinical Research and Field Studies of Infectious Diseases Study Section (CRFS)	Total Cost	
		Indirect Cost	
Program Officer	Stemmy, Erik J		

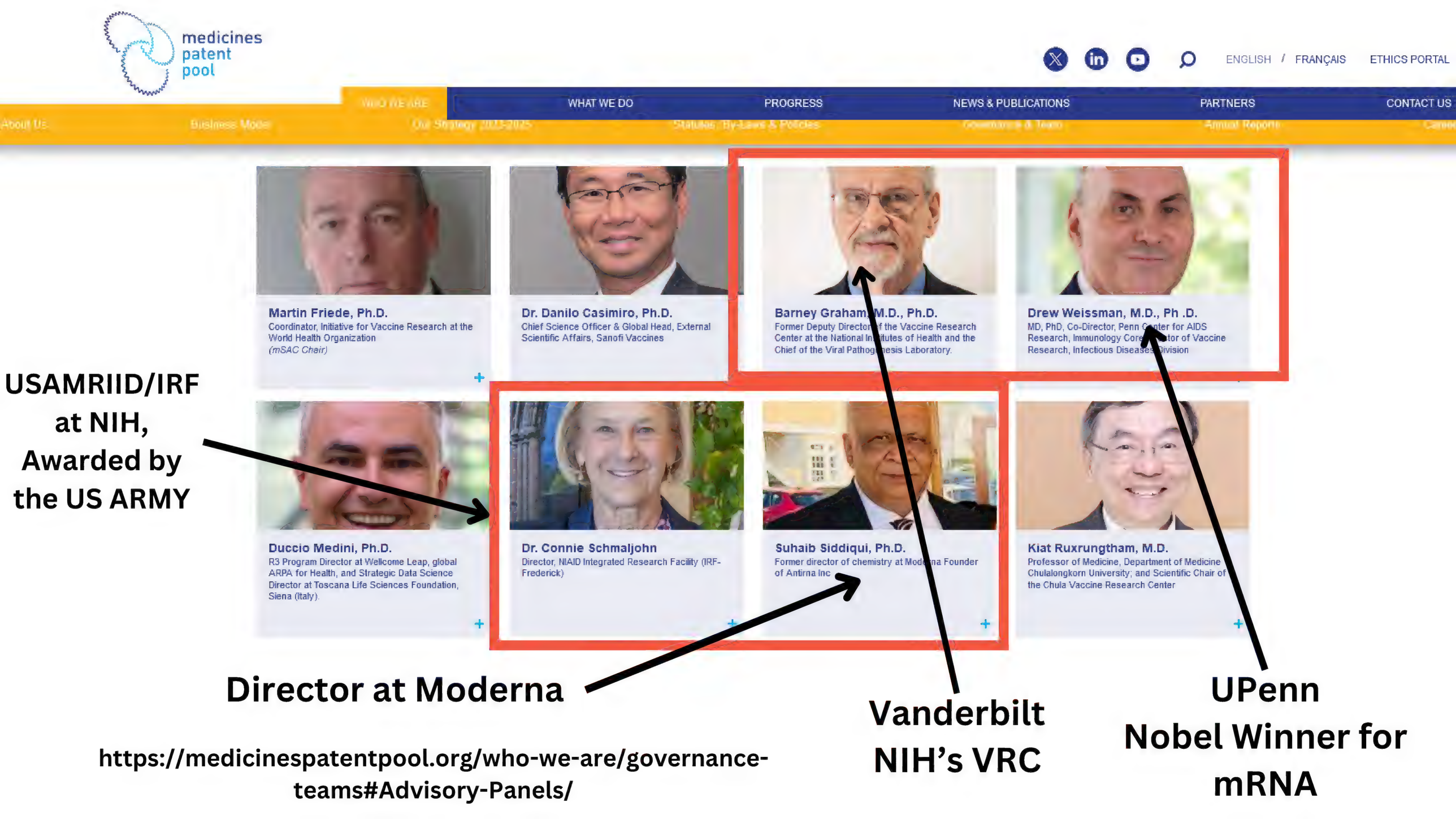
Institution

Name	Ecohealth Alliance, Inc.	City	New York
Department		State	NY
Type		Country	United States
DUNS #	077090066	Zip Code	10001

T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC
RBD recombinant protein-based SARS vaccine for biodefense								
5 R01AI098775-02			HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2013	NIAID	NIAID	$1,085,321
Epidemiology and modeling of the population dynamics of influenza and antimicrobi								
5 K01AI101010-02			GOLDSTEIN, EDWARD	HARVARD SCHOOL OF PUBLIC HEALTH	2013	NIAID	NIAID	$126,873
RBD recombinant protein-based SARS vaccine for biodefense								
3 R01AI098775-02S1			HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2013	NIAID	NIAID	$3,936
Mechanisms of viral proteases in coronavirus replication and pathogenesis								
5 R01AI085089-04			BAKER, SUSAN C. MESECAR, ANDREW D	LOYOLA UNIVERSITY CHICAGO	2013	NIAID	NIAID	$712,986
Role of the Epithelial Growth Factor Receptor in SARS Coronavirus Pathogenesis								
5 R01AI095569-03			FRIEMAN, MATTHEW BRYAN	UNIVERSITY OF MARYLAND BALTIMORE	2013	NIAID	NIAID	$485,623
Epidemiology, transmission, and phylogenetics of influenza in a tropical country								
5 U01AI088654-04			HARRIS, EVA GORDON, AUBREE L	UNIVERSITY OF CALIFORNIA BERKELEY	2013	NIAID	NIAID	$702,118
Analysis of Coronavirus-Host Cell Interactions								
5 R01AI099107-02			MAKINO, SHINJI	UNIVERSITY OF TEXAS MED BR GALVESTON	2013	NIAID	NIAID	$359,550

Receptor recognition mechanisms of coronaviruses						
5 R01 AI089728-04	LI, FANG	UNIVERSITY OF MINNESOTA	2013	NIAID	NIAID	$351,302
Structure and Mechanism of Programmed Ribosomal Frameshifting in SARS coronavirus						
1 R01 AI104711-01	D'SOUZA, VICTORIA MANUEL	HARVARD UNIVERSITY	2013	NIAID	NIAID	$357,435
Determinants of Coronavirus Fidelity in Replication and Pathogenesis						
1 R01 AI108197-01	DENISON, MARK R BARIC, RALPH S	VANDERBILT UNIVERSITY	2013	NIAID	NIAID	$560,000
PPG: SARS-CoV-host cell interactions and vaccine development						
5 P01 AI060699-08	PERLMAN, STANLEY	UNIVERSITY OF IOWA	2013	NIAID	NIAID	$1,605,748
Evaluation of SARS-CoV 2'O Methyltransferase Mutants						
1 F32 AI102561-01A1	MENACHERY, VINEET D	UNIV OF NORTH CAROLINA CHAPEL HILL	2013	NIAID	NIAID	$52,190
Role of anti-SARS-CoV T cell response in pathogenesis						
5 R01 AI091322-03	PERLMAN, STANLEY	UNIVERSITY OF IOWA	2013	NIAID	NIAID	$354,850
Broad Spectrum Neutralizing Human Abs to SARS and Related Coronaviruses						
5 R01 AI085524-04	MARASCO, WAYNE A.	DANA-FARBER CANCER INST	2013	NIAID	NIAID	$1,025,389
Mechanisms of viral proteases in coronavirus replication and pathogenesis						
5 R01 AI085089-05	BAKER, SUSAN C. MESECAR, ANDREW D	LOYOLA UNIVERSITY CHICAGO	2014	NIAID	NIAID	$602,456

Understanding the Risk of Bat Coronavirus Emergence						
1 R01AI110964-01	DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2014	NIAID	NIAID	$666,442
Role of anti-SARS-CoV T cell response in pathogenesis						
5 R01AI091322-04	PERLMAN, STANLEY	UNIVERSITY OF IOWA	2014	NIAID	NIAID	$377,500
Receptor recognition mechanisms of coronaviruses						
5 R01AI089728-05	LI, FANG	UNIVERSITY OF MINNESOTA	2014	NIAID	NIAID	$373,725
RBD recombinant protein-based SARS vaccine for biodefense						
5 R01AI098775-03	HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2014	NIAID	NIAID	$1,134,359
Role of the Epithelial Growth Factor Receptor in SARS Coronavirus Pathogenesis						
5 R01AI095569-04	FRIEMAN, MATTHEW BRYAN	UNIVERSITY OF MARYLAND BALTIMORE	2014	NIAID	NIAID	$528,500
Analysis of Coronavirus-Host Cell Interactions						
3 R01AI099107-03S1	MAKINO, SHINJI	UNIVERSITY OF TEXAS MED BR GALVESTON	2014	NIAID	NIAID	$30,327
RBD recombinant protein-based SARS vaccine for biodefense						
3 R01AI098775-03S1	HOTEZ, PETER J BOTTAZZI, MARIA ELENA JIANG, SHIBO	BAYLOR COLLEGE OF MEDICINE	2014	NIAID	NIAID	$3,936
Deciphering the Role of the Coronavirus Macro Domain in SARS-CoV Infection						
1 F32AI113973-01	FEHR, ANTHONY R	UNIVERSITY OF IOWA	2014	NIAID	NIAID	$53,282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Annual Reports
Careers
Martin Friede, Ph.D.
Coordinator, Initiative for Vaccine Research at the World Health Organization
(mSAC Chair)
Dr. Danilo Casimiro, Ph.D.
Chief Science Officer & Global Head, External Scientific Affairs, Sanofi Vaccines
Barney Graham, M.D., Ph.D.
Former Deputy Director of the Vaccine Research Center at the National Institutes of Health and the Chief of the Viral Pathogenesis Laboratory.
Drew Weissman, M.D., Ph .D.
MD, PhD, Co-Director, Penn Center for AIDS Research, Immunology Core, Director of Vaccine Research, Infectious Diseases Division
Duccio Medini, Ph.D.
R3 Program Director at Wellcome Leap, global ARPA for Health, and Strategic Data Science Director at Toscana Life Sciences Foundation, Siena (Italy).
Dr. Connie Schmaljohn
Director, NIAID Integrated Research Facility (IRF-Frederick)
Suhaib Siddiqui, Ph.D.
Former director of chemistry at Moderna Founder of Antirna Inc
Kiat Ruxrungtham, M.D.
Professor of Medicine, Department of Medicine Chulalongkorn University; and Scientific Chair of the Chula Vaccine Research Center
USAMRIID/IRF at NIH, Awarded by the US ARMY
Director at Moderna
Vanderbilt NIH's VRC
UPenn Nobel Winner for mRNA
https://medicinespatentpool.org/who-we-are/governance-teams#Advisory-Panels/

Integrated Research Facility at Fort Detrick
About the IRF-Frederick
Leadership and Scientists
Research > Integrated Research Facility at Fort Detrick

Integrated Research Facility Leadership and Scientists

https://www.niaid.nih.gov/research/integrated-research-facility-leadership-scientists

IRF-Frederick Leadership

Connie Schmaljohn, Ph.D.

Director, Integrated Research Facility at Fort Detrick

Contracting Officer's Representative (COR)

Contact: For contact information, search the NIH Enterprise Directory.

Dr. Connie Schmaljohn was selected and became Director, IRF-Frederick in November 2019. Prior to that time, she was Senior Research Scientist for Medical Defenses Against Infectious Disease Threats and directed a research program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Dr. Schmaljohn earned a B.S. degree in microbiology from the University of Nebraska and a...

Biography

Dr. Connie Schmaljohn was selected and became Director, IRF-Frederick in November 2019. Prior to that time, she was Senior Research Scientist for Medical Defenses Against Infectious Disease Threats and directed a research program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

Dr. Schmaljohn earned a B.S. degree in microbiology from the University of Nebraska and a Ph.D. in virology from Colorado State University, after which she joined USAMRIID as a National Research Council postdoctoral fellow. Her subsequent positions at USAMRIID included Principal Investigator as well as Chief, Molecular Virology Branch. Dr. Schmaljohn's research background is in molecular virology and molecular vaccine development. She has served as president of the International Society of Hantaviruses, chair of the American Society for Microbiology Biodefense Conference, and chair of the International Committee on the Taxonomy of Viruses *Bunyaviridae* Study Group. She also has served on the Interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Viral Hemorrhagic Fevers Integrated Product Team (IPT), the Board of Scientific Counselors for the NIAID Vaccine Research Center, and the Scientific Advisory Council for the Coalition of Emergency Preparedness Innovations (CEPI). She was elected to the American Academy of Microbiology (2007) and was selected as fellow of the International Society for Vaccines (2015). She received the Order of Military Merit (2002), the Association of Military Surgeons of the United States Research Award (2002), the University of Nebraska Alumni Achievement Award (2012), and the Presidential Rank Award (2017).

U.S. ARMY

U.S. ARMY

Dr. Connie S. Schmaljohn of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has been awarded the Meritorious Senior Professional Rank Award for the Department of the Army for 2017.

Schmaljohn is Senior Research Scientist for Medical Defense Against Infectious Disease Threats (ST) at USAMRIID and her research involves developing medical countermeasures against highly lethal viruses of military importance. She was instrumental in the discovery of hantaviruses, a previously unknown class of rodent-borne viruses that cause hemorrhagic fever or severe respiratory

https://www.army.mil/article/210940/usamriids_schmaljohn_receives_presidential_rank_award

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Therapure Biomanufacturing Signs Manufacturing Deal With VBI Vaccines for Coronavirus Vaccine Candidates

August 18, 2020 09:04 AM Eastern Daylight Time

MISSISSAUGA, Ontario--(BUSINESS WIRE)--Therapure Biomanufacturing, a division of Therapure Biopharma Inc., announced today the signing of an agreement with VBI Vaccines Inc. for the manufacture of their coronavirus vaccine candidates. Therapure Biomanufacturing is an integrated contract development and manufacturing organization (CDMO) focused on biologic and high value therapeutics that can provide new options for patient care. Under this agreement, Therapure will be responsible for the biomanufacturing of the vaccine drug substance as well as the aseptic fill of the drug product at the Therapure facility in Mississauga, Ontario.

Mr. Safa'a Al-Rais, Therapure's Chief Operating Officer, said: "We are delighted to partner with VBI to assist with providing an effective response to the ongoing COVID-19 pandemic through Therapure's biomanufacturing and aseptic fill finish services for VBI's innovative COVID-19 vaccine candidates, which utilize their flexible enveloped virus-like particle (eVLP) platform technology. Therapure prides itself on its development, clinical and commercial cGMP manufacturing expertise providing solutions for biologic therapeutics and innovative drug delivery technologies, which make a difference in patients' lives."

"We look forward to working with Therapure to address the ongoing public health challenge," said Jeff Baxter, VBI's President and CEO. "Therapure's proven cGMP biomanufacturing capabilities and expertise with aseptic fill finish make them a great partner as we advance our vaccine candidate into and through clinical studies."

ABOUT THERAPURE BIOMANUFACTURING

Therapure Biomanufacturing is the award-winning contract development and manufacturing division of Therapure Biopharma Inc. offering integrated services for developing, manufacturing, purifying and packaging complex biological therapeutics and technologies. Our scientific and manufacturing expertise, as well as our flexible state-of-the-art facility with a successful regulatory track record including an FDA approval for commercial manufacturing, provides clients with optimal biomanufacturing solutions to advance their

https://www.businesswire.com/news/home/20200818005214/en/Therapure-Biomanufacturing-Signs-Manufacturing-Deal-VBI-Vaccines

https://www.vbivaccines.com/press-releases/cepi-collaboration/

VBI VACCINES

Coronavirus | Press Releases

CEPI and VBI Vaccines Collaborate to Advance Vaccine Candidates Against COVID-19 Variants

March 10, 2021

- *Up to $33m of funding will support development of VBI's enveloped virus-like particle (eVLP) vaccine candidates against COVID-19 variants of concern.*
- *Phase 1 clinical study of VBI's eVLP vaccine candidate, VBI-2905, targeting the B.1.351 variant, anticipated to initiate mid-year 2021.*

CEPI, the Coalition for Epidemic Preparedness Innovations, and VBI Vaccines Inc. (Nasdaq: VBIV), today announced a partnership to

Commercial Advisory Board

Meet Our Commercial Advisors

This Board, comprised of public health policy, epidemiology, and vaccine development experts, works closely with our management team to provide guidance for the pre-launch and commercialization strategy of our pipeline programs.

Damian Braga
Director, Chair of Commercial Advisory Board

United States

Eddy A. Bresnitz, M.D., M.S.C.E.

Michael D. Decker, M.D., M.P.H.

John D. Grabenstein, Ph.D., R.Ph.

Eddy A. Breshitz, M.D., M.S.C.E.

Michael D. Decker, M.D., M.P.H.

John D. Grabenstein, Ph.D., R.Ph.

Michael D. Decker, M.D., M.P.H.

Current Adjunct Professor of Preventive Medicine at Vanderbilt University Medical Center, Dr. Decker is a well-published expert on vaccines, preventive medicine, and public health policy. In 2016, Dr. Decker retired from Sanofi Pasteur after more than 15 years, where he was Vice President and Global Medical Expert from 2013-2016 and Vice President, Scientific and Medical Affairs, and Chief Medical Officer, Sanofi Pasteur U.S., from 2000-2012. From 1984-2000, Dr. Decker was a Professor of Preventive Medicine and Medicine (Infectious Diseases) at Vanderbilt University School of Medicine. He has also previously served as a Medical Officer in the U.S. Public Health Service at the Centers for Disease Control and Prevention (CDC), as Editor-in-Chief of the journal Infection Control and Hospital Epidemiology from 1993 to 2001, and as Co-Editor of the International Journal of Health Governance from 2016 to 2020.

< Sanofi, CDC, Vanderbilt

David E. Anderson, Ph.D.

Chief Scientific Officer

A dynamic and well-published immunologist with broad expertise in the areas of vaccine development, autoimmunity and tumor immunology, Dr. Anderson joined VBI full time in 2009 from Harvard Medical School, where he held a position as Assistant Professor. As a co-founder and Chief Scientific Officer of VBI, Dr. Anderson is an inventor of much of the Company's intellectual property and actively manages its ongoing expansion. Dr. Anderson holds a Ph.D. from Harvard University and a B.S. from the University of California at Davis.

Harvard + UC Davis>

Scientific and Clinical Advisory Boards

Meet Our Scientific and Clinical Advisors

These highly-regarded global experts in infectious disease, immuno-oncology, and vaccine development help guide the advancement and direction of our pipeline programs.

Michel De Wilde, Ph.D.
Director, Chair of Scientific and Clinical Advisory Boards

Hepatitis B Virus (HBV)

Adam Finn, M.D., Ph.D.

Peter A. Patriarca, M.D.

Daniel Shouval, M.D.

Bruce Smith, Ph.D.

Stefan Thoelen, M.D.

Pierre Van Damme, M.D., Ph.D.

Glioblastoma (GBM)

Denis R. Burger, Ph.D.

Michael Lim, M.D.

Allen Waziri, M.D.

Patrick Yung Wen, M.D.

Cytomegalovirus (CMV)

Robert Pass, M.D.

Stanley Plotkin, M.D.

VBI VACCINES

Eddy A. Bresnitz, M.D., M.S.C.E.

John D. Grabenstein, Ph.D., R.Ph.

Dr. Grabenstein is a global vaccinologist, pharmacist, epidemiologist, and public-health leader specializing in adult vaccines, implementation, and vaccine history. Currently, Dr. Grabenstein is president of consulting service Vaccine Dynamics SP, and is also Associate Director of Scientific Communications for the Immunization Action Coalition (IAC), a non-profit organization working to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public. Previously, he spent over 13 years at Merck Vaccines, most recently serving as Global Executive Director of Medical Affairs until his retirement in late 2019. Before joining Merck, Dr. Grabenstein served for 27 years in the U.S. Army Medical Department, achieving the rank of Colonel. From 1999 to 2006, he directed the scientific elements of the U.S. Department of Defense (DoD) anthrax and smallpox vaccination programs. As Director, Military Vaccine Agency, he was responsible for science, communication, education, and safety surveillance of military immunizations for 2.6 million U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard personnel deployed globally.

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Steven Gillis, Ph.D.

Chairman of the Board

Steven Gillis, Ph.D., has been a Managing Director of ARCH Venture Partners since 2006 and joined the firm in 2005. Dr. Gillis is focused on the evaluation of new life science technologies and also on the development and growth of ARCH's biotechnology portfolio companies. He is a director of Takeda Pharmaceutical Co. Ltd. (TAK), Homology Medicines, Inc. (FIXX), and also serves as Chairman of Codiak Biosciences (CDAK). Dr. Gillis represents ARCH as a managing director and serves as Chairman of a number of ARCH's private, biotechnology portfolio companies.

Dr. Gillis was a founder and director of Corixa Corporation and served as CEO from its inception and as its Chairman from 1999 until its acquisition in 2005 by GlaxoSmithKline. Prior to Corixa, Dr. Gillis was a founder and director of Immunex Corp. From 1981 until his departure in 1994, Dr. Gillis served as Immunex's Director of Research and Development, Chief Scientific Officer, and as CEO of Immunex's R&D subsidiary. Dr. Gillis was interim CEO of Immunex Corp. following its majority purchase by American Cyanamid Company and remained a member of the board until 1997. Amgen, Inc. acquired Immunex in 2002.

Dr. Gillis is an immunologist by training with over 300 peer-reviewed publications in the areas of molecular and tumor immunology. He is credited as being a pioneer in the field of cytokines and cytokine receptors, directing the development of multiple marketed products including Leukine, (GM-CSF), Prokine (IL-2) and Enbrel (soluble TNF receptor-Fc fusion protein) as well as the regulatory approval of Bexxar (radiolabeled anti-CD20). Dr. Gillis received a B.A. from Williams College and a Ph.D. from Dartmouth College.

< ARCH VENTURES
Takeda
GSK
Immunex
[prior to acquisition by Amgen,]
DARTHMOUTH

Michel De Wilde, Ph.D.

Director

Michel De Wilde, Ph.D., was Senior Vice President, Research & Development, at Sanofi Pasteur, the human vaccines division of Sanofi from 2001 until June 2013. In this position, he was responsible for managing approximately 1,500 employees and a broad portfolio of approximately 20 development projects.

Prior to joining Sanofi Pasteur in January 2000, Dr. De Wilde was at SmithKline Beecham Biologicals (now GSK Vaccines) in Rixensart, Belgium. Dr. De Wilde joined the group in 1978 as a research scientist upon formation of a unit focusing on the application of recombinant DNA technology to vaccine development. He subsequently held positions of increasing responsibility and, as Vice President, Research & Development at Sanofi Pasteur, headed a team of approximately 400 specialists, active in all aspects of preclinical vaccine development.

Dr. De Wilde a member of a number of Scientific Advisory Boards, including COVAX Independent Product Group and other COVID related advisory bodies.

Dr. De Wilde received his degree in Chemistry from the Free University of Brussels in 1971, followed by a Ph.D. in Biochemistry in 1976. He carried out postdoctoral work at the University of Wisconsin, Madison (U.S.) and the University of Ghent (Belgium). Dr. De Wilde authored over 50 publications during the early part of his career.

^Sanofi, GSK, COVAX, University of Wisconsin Madison

VBI VACCINES

John D. Grabenstein, Ph.D., R.Ph.

Dr. Grabenstein is a global vaccinologist, pharmacist, epidemiologist, and public-health leader specializing in adult vaccines, implementation, and vaccine history. Currently, Dr. Grabenstein is president of consulting service Vaccine Dynamics SP, and is also Associate Director of Scientific Communications for the Immunization Action Coalition (IAC), a non-profit organization working to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public. Previously, he spent over 13 years at Merck Vaccines, most recently serving as Global Executive Director of Medical Affairs until his retirement in late 2019. Before joining Merck, Dr. Grabenstein served for 27 years in the U.S. Army Medical Department, achieving the rank of Colonel. From 1999 to 2006, he directed the scientific elements of the U.S. Department of Defense (DoD) anthrax and smallpox vaccination programs. As Director, Military Vaccine Agency, he was responsible for science, communication, education, and safety surveillance of military immunizations for 2.6 million U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard personnel deployed globally.

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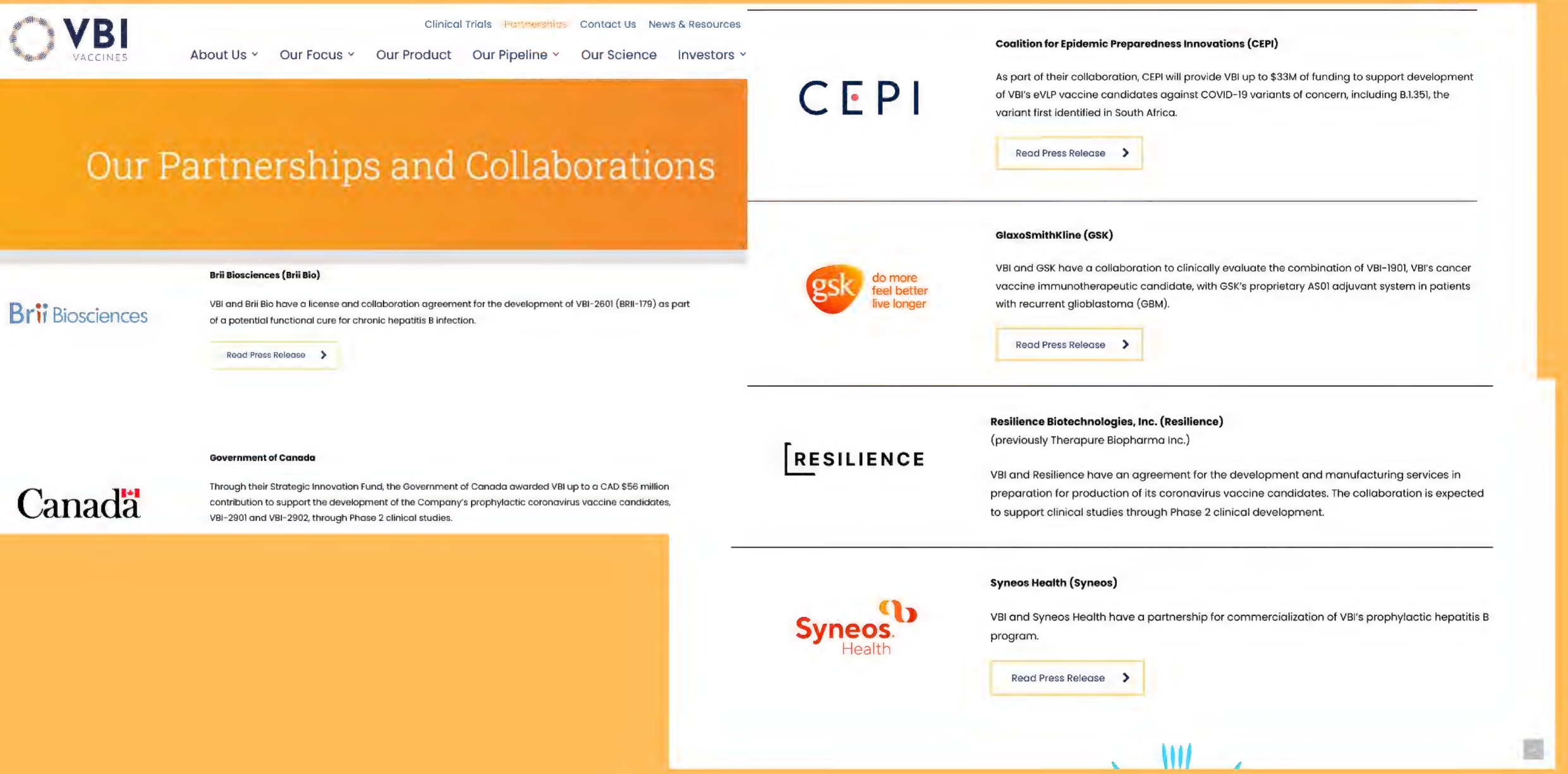
https://www.vbivaccines.com/partnerships/

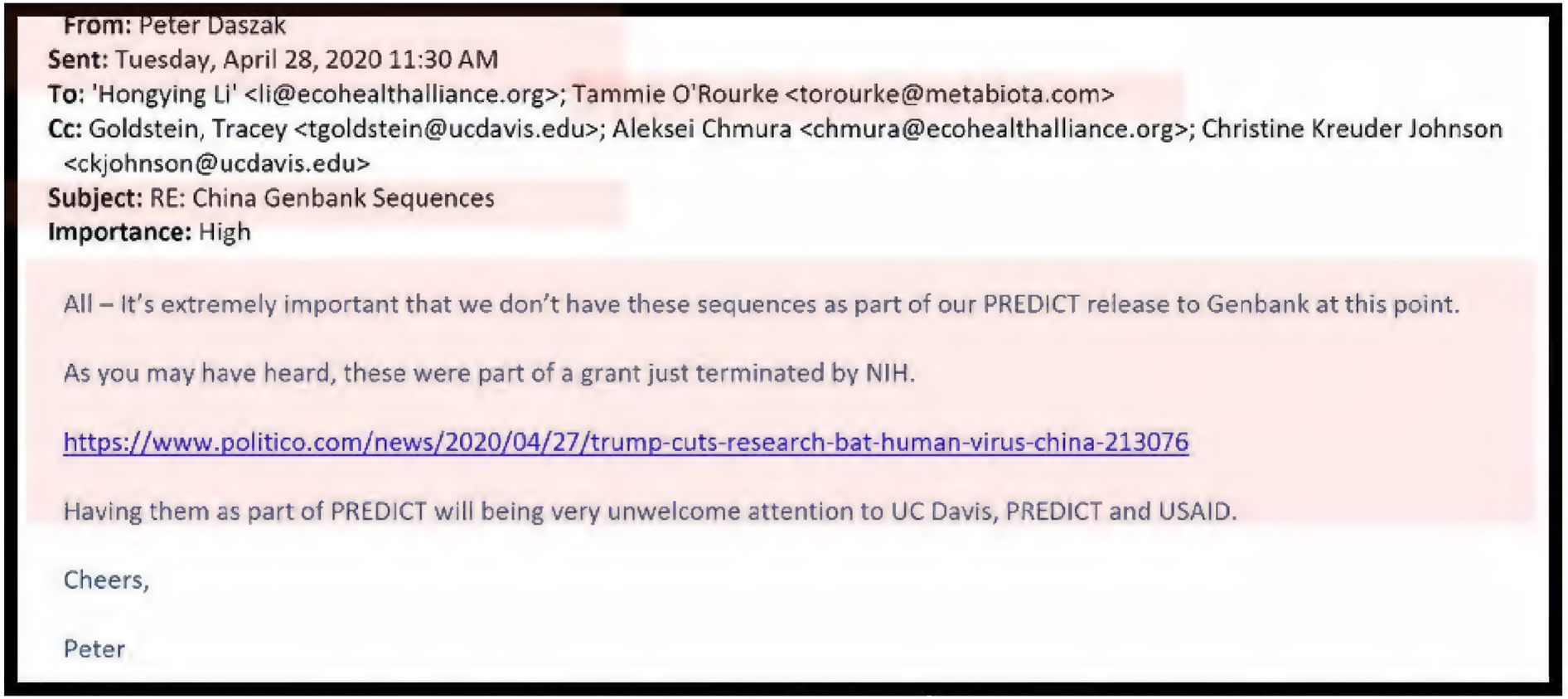


President (Term: 2022-2024)
John D. Grabenstein, RPh, PhD, ScD (Hon), is a globally recognized vaccinologist, pharmac
300 articles and 11 books, primarily on topics of immunization, public health, and leadershi
a consultancy providing services related to human vaccines, antibody products, and other immunologic drugs. He also serves as the Managing Editor of *IZ Express*, the newsletter of Immune.org.

Dr. Grabenstein received his pharmacy degree from Duquesne University, a master's degree in education from Boston University, and a doctorate in epidemiology at the University of North Carolina. He was elected to the National Academy of Medicine in 2021 and is a Fellow of the Royal Society for Public Health. Dr. Grabenstein is the 2020 recipient of APhA's Remington Honor Medal, American pharmacy's highest honor for distinguished service. An AIHP member since 1994, Dr. Grabenstein joined the Institute's Board of Directors in 2018, served as Vice President from 2020-21, and became the organization's President in November 2021.

Dr. Grabenstein's prior positions include Global Director of Medical Affairs for Merck Vaccines (where he led medical-affairs and scientific-policy activities for a global enterprise that provided 180 million doses annually for 13 vaccines) and Director of the U.S. Department of Defense's Military Vaccine Agency (where he oversaw the Defense Department immunization programs for 9 million troops, retirees, and family members spread across four continents and dozens of ships at sea).

https://aihp.org/about/aihp-board-of-directors/



From: Peter Daszak
Sent: Tuesday, April 28, 2020 11:30 AM
To: 'Hongying Li' <li@ecohealthalliance.org>; Tammie O'Rourke <torourke@metabiota.com>
Cc: Goldstein, Tracey <tgoldstein@ucdavis.edu>; Aleksei Chmura <chmura@ecohealthalliance.org>; Christine Kreuder Johnson <ckjohnson@ucdavis.edu>
Subject: RE: China Genbank Sequences
Importance: High

All – It's extremely important that we don't have these sequences as part of our PREDICT release to Genbank at this point.

As you may have heard, these were part of a grant just terminated by NIH.

https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076

Having them as part of PREDICT will being very unwelcome attention to UC Davis, PREDICT and USAID.

Cheers,

Peter

This email from Daszak was sent out to EHA and Metabiota staff urging them not to publish Viral Sequences to Genbank for fear it would bring "very unwelcome attention to UC Davis, PREDICT and USAID"

USAID is a CIA front. The CIA's investment arm, In-Q-Tel is a major funder of Hunter Biden's failed Metabiota.

This email occurred 3 weeks BEFORE EHA & Wuhan decided to upload SHC014 [Close chimeric relative to SARS2] to Genbank after 5 years! [May 22 2020]

https://sciencex.com/wire-news/56829642/dana-farber-receive-56-million-grant-to-develop-rapid-countermea.html

Dana-Farber receive $5.6 million grant to develop rapid countermeasures to infectious agents

January 18th, 2011

BOSTON--Researchers at Dana-Farber Cancer Institute have received a $5.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and the Army Research Office (ARO) to develop transient immunity against known, unknown, naturally occurring, or engineered disease-causing pathogens. The ultimate goal is to develop a viable countermeasure to an unknown pathogen within seven days of receiving it in a laboratory.

Wayne Marasco of the NIH's Vaccine Research Center working with in 2011 DARPA for;

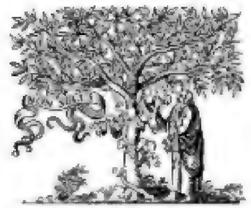
"This grant will support revolutionary advances in rapid response to naturally evolving AND ENGINEERED PATHOGENS."

BOSTON--Researchers at Dana-Farber Cancer Institute have received a $5.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and the Army Research Office (ARO) to develop transient immunity against known, unknown, naturally occurring, or engineered disease-causing pathogens. The ultimate goal is to develop a viable countermeasure to an unknown pathogen within seven days of receiving it in a laboratory.

Wayne A. Marasco, MD, PhD, of the Department of Cancer Immunology and AIDS at Dana-Farber and an associate professor of Medicine at Harvard Medical School, is the project's principal investigator.

Since the mid 1990's, DARPA's Defense Sciences Office has pioneered advances across the full spectrum of bio-warfare defense needs, including the development of advanced diagnostics and medical therapies that are active against an entire range of infectious agents.

"This grant will support revolutionary advances in rapid response to naturally evolving and engineered pathogens," says Marasco. "DARPA has issued a challenge to develop a treatment to unknown threats in just seven days, and we are excited about the opportunity to meet this challenge."



ELSEVIER

Journal of Immunological Methods 246 (2000) 97–108

JIM
Journal of Immunological Methods

www.elsevier.nl/locate/jim

Expression of a human, neutralizing monoclonal antibody specific to Puumala virus G2-protein in stably-transformed insect cells

Mary C. Guttieri*, Carol Bookwalter, Connie Schmaljohn

Virology Division, United States Army Medical Research Institute of Infectious Diseases, Bldg. 1301, Fort Detrick, Frederick, MD 21702-5011, USA

Received 29 May 2000; received in revised form 12 September 2000; accepted 13 September 2000

Strange how Metabiota's Guttieri collaborated with USAMRIID/IRFs Schmaljohn on Monoclonal Antibodies at Fort Detrick in 2000

https://www.uvm.edu/~cbookwal/296c/guttieri.pdf

Therapure Biopharma Awarded US Government Contract

News Published: June 20, 2013

Therapure Biopharma Inc. has announced the company will participate as a subcontractor for DynPort Vaccine Company LLC (DVC), a CSC company, that was awarded a US cost-plus-fixed-fee contract with a maximum value of $157.3 million (prime contract number W911QY-13-C-0056) by the US Department of Defense (DoD) to support the development of a prophylactic countermeasure to prevent the effects of organophosphorus nerve agent poisoning.

https://www.technologynetworks.com/drug-discovery/news/therapure-biopharma-awarded-us-government-contract-211685

https://www.pharmaceutical-technology.com/contractors/contract-manufacturers/therapure-biopharma/pressreleases/presstherapure-biopharma-awarded-us-government-contract-for-development-of-anti-nerve-gas-agent/

Therapure Biopharma

Therapure Biopharma Awarded US Government Contract for Development of Anti-Nerve Gas Agent

Make an enquiry

Therapure Biopharma, a contract development and manufacturing organization (CDMO) of biotherapeutics, is pleased to announce that the company will participate as a subcontractor for DynPort Vaccine Company (DVC), a CSC company, that was awarded a US cost-plus-fixed-fee contract with a maximum value of $157.3m (prime contract number W911QY-13-C-0056) by the US Department of Defense (DoD) to support the development of a prophylactic countermeasure to prevent the effects of organophosphorus nerve agent poisoning.

Therapure's subcontract under the above prime contract includes process optimization as well as manufacture of all clinical and nonclinical materials (drug product) to support DVC's contract to develop, test and obtain the US Food and Drug Administration (FDA) approval for human plasma-derived butyrylcholinesterase (HuBChE), a blood plasma protein that binds and inactivates nerve agents. Mr Nick Green, therapure's president and chief executive officer, said; "We are delighted to partner with DVC to develop and manufacture medical counter measures for the US Department of Defense as part of a defense strategy against a wide range of nerve gases. Therapure successfully completed a rigorous selection and approval process to serve as the manufacturing subcontractor under the prime contract, which is a testament to the company's standards and capabilities in biomanufacturing. It is an honor to be part of this very critical initiative to protect US Servicemen and women."

Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the US Department of Defense, Department of the Army, Chemical Biological Medical Systems Joint Project Management Office (CBMS JPMO), Medical Identification and Treatment Systems Joint Product Management Office (MITS JPMO).

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RESILIENCE BIOTECHNOLOGIES INC.

Company Number	BC1259445
Status	Active
Incorporation Date	30 July 2020 (almost 3 years ago)
Company Type	BC Company
Jurisdiction	British Columbia (Canada)
Business Number	720950070
Registry Page	https://www.orgbook.gov.bc.ca/entity/...

Latest Events

- **2020-07-30** Incorporated

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Recent filings for RESILIENCE BIOTECHNOLOGIES INC.

1 Oct 2020 NOTICE OF ALTERATION

Source *OrgBook BC, https://www.orgbook.gov.bc.ca/search, 1 Jul 2023*

JULY 30 2020

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Resilience Receives USD $164 Million Investment from the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness

RESILIENCE

NATIONAL RESILIENCE, INC.

- **Headquarters:** San Diego, California, US
- **Website:** www.resilience.com
- **CEO:** Rahul Singhvi
- **Employees:** 1,600
- **Organization:** PRI

Release Summary

businesswire
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Safa'a Al-Rais, Chief Operating Officer at Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI), a subsidiary of National Resilience, Inc. (Resilience), discusses the Canadian Government's CAD 199.2 million ($163.8 million) investment in the site, through the Strategic Innovation Fund. The investment will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.

RESILIENCE

May 18, 2021 12:15 PM Eastern Daylight Time

SAN DIEGO & BOSTON--(BUSINESS WIRE)--National Resilience, Inc. (Resilience), a company building the world's most advanced biopharmaceutical manufacturing ecosystem, announced that the Government of Canada will invest CAD 199.2 million ($163.8 million), through the Strategic Innovation Fund, in the company's Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI) to modernize and expand production capacity.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases"

Tweet this

This project will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are now being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases," said Rahul Singhvi, Sc.D, Chief Executive Officer of Resilience. "This partnership with the Government of Canada will help prepare Canada for future pandemics and strengthen the country's biopharmaceutical ecosystem."

"The Government of Canada's top priority is to protect the health and safety of Canadians. Today's contribution to Resilience Biotechnologies Inc. is another important step to support Canada's leadership in the life sciences sector and to build future pandemic preparedness. These investments are also creating well-paying jobs and helping to grow Canada's life sciences ecosystem as an engine

MAY 18 2021

RESILIENCE BIOTECHNOLOGIES INC IS THE ONTARIO BASED SUBSIDIARY OF NATIONAL RESILIENCE INC

THE GOVERNMENT OF CANADA INVESTED $163.8M

Resilience (Durham)

National Resilience manufactures viral vectors, a component of cell and gene therapies.

https://resilience.com

1733 T W. Alexander Drive
Durham NC 27703

Phone (984) 202-0854

County Durham

Region Triangle

Company Details

Company type
Bioscience Company

Year founded
2020

Employment range in NC
100-199

US headquarters
California

Global headquarters
United States

Primary site activity
Production and Manufacturing

All company activities
Production and Manufacturing

Core capabilities
Gene Therapy
Formulation or Fill and Finish

Potential end market(s)
Therapeutics - Gene- and Cell-based Therapies
Therapeutics - Large Molecule (biologics)
Cancers and other Neoplasms
Congenital and Genetic Diseases

https://bioprocessintl.com › bioprocess-insider › canada-pays-164-million-to-add-resilience

Canada adds Resilience to pandemic prep for $164 - BioProcess .

Canada has called on **Resilience Biotechnologies** to boost local COVID-19 shot capacity. The Canadian Government has given contract development manufacturing organization (CDMO) **Resilience Biotechnologies** $164 million to modernize its recently acquired Ontario plant as par of a wider pandemic preparedness effort.

https://directory.ncbiotech.org › company › resilience-durham

Resilience (Durham) | North Carolina Biotech Center

National Resilience manufactures viral vectors, a component of cell and gene therapies.

https://www.lobbycanada.gc.ca › app › secure › ocl › lrs › do › vwRg?cno=368948

Registration - In-house Corporation - Commissioner of Lobbying ..

In-house Corporation Details Description of activities **Resilience Biotechnologies** (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics.

https://www.theofficialboard.com › news › resilience-biotechnologies

News at Resilience Biotechnologies - The Official Board

Jun 8, 2022 · **Resilience Biotechnologies** has 2,177 competitors including Eurofins (Luxembourg

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A public directory of organizations registered in BC

RESILIENCE BIOTECHNOLOGIES INC.

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Filters

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RESILIENCE BIOTECHNOLOGIES INC.
BC Company
Business number: 720950070
Incorporation number: BC1259445

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Registration

RESILIENCE BIOTECHNOLOGIES INC. is a
BC Company

Incorporation number: BC1259445
Registered on: Jul 29, 2020
Business name effective: Jul 29, 2020

Registration - In-house Corporation

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Resilience Biotechnologies, Inc. / Sankalp Vashishtha, Vice President / General Manager

Registration Information

In-house Corporation name: **Resilience Biotechnologies, Inc.**
Responsible Officer Name: **Sankalp Vashishtha, Vice President / General Manager**
Responsible Officer Change History
Initial registration start date: **2021-02-24**
Registration status: **Active**
Registration Number: **953057-368948**

Associated Communications

Total Number of Communication Reports: **0**

Monthly communication reports in the last 6 months: **0**

Registration versions: 5 of 5: 2023-02-20 to present

Version 5 of 5 (2023-02-20 to present)

Lobbying Information | **In-house Corporation Details** | **Lobbyists Details**

Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Vice President / General Manager

Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Chief Operating Officer, interim

Government funding

End date of the last completed financial year: 2021-12-31

Government Institution	Funding Received in Last Financial Year	Funding Expected in Current Financial Year
National Research Council (NRC)	$2,063,196.23	Yes

In-house Corporation Contact Information

Address:
2585 Meadowpine Blvd.
Mississauga, ON L5N 8H9
Canada

Telephone number: 905-286-6200

Parent Company Information

- National Resilience, Inc.
  - 9310 Athena Circle, Suite 130
    La Jolla, CA 92037
    United States of America

Subsidiary Beneficiary Information

Resilience Biotechnologies, Inc. does not have any subsidiaries that could have a direct interest in the outcome of the undertaking

ORGANIZATION

Therapure Biopharma

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About

Therapure is an integrated Contract Development and Manufacturing Organization.

Acquired by
3SBio Inc.

Mississauga
251-500
Private
www.therapurebio.com/

Highlights

Contacts
54

Employee Profiles
1

Similar Companies
3

Recent News & Activity

News • Aug 11, 2020
PharmiWeb.com — **Global Artificial Blood Substitutes Market**

Acquisition • Sep 3, 2017
3SBio Inc. acquired **Therapure Biopharma** for **$290,000,000**
Discover more acquisitions

Details

Industries
Manufacturing

Founded Date
2008

Operating Status
Active

Company Type
For Profit

Contact Email
info@therapurebio.com

Phone Number
1(905)286-6200

At Therapure Biopharma Inc. they're specialists in biologics therapeutics, and they act on a passion for enhancing patient care through their three divisions: Therapure Biomanufacturing, Therapure Innovations and Therapure Biologics.

Recent News & Activity

Number of Articles
1

News • Aug 11, 2020
PharmiWeb.com — **Global Artificial Blood Substitutes Market**

Acquisition • Sep 3, 2017
3SBio Inc. acquired **Therapure Biopharma** for **$290,000,000**
Discover more acquisitions

M&A Details

Therapure Biopharma was acquired by **3SBio Inc.** for $290M on Sep 3, 2017.

Transaction Name
Therapure Biopharma acquired by ...

Acquired by
3SBio Inc.

Announced Date
Sep 3, 2017

Price
$290M

3SBio Inc.

Summary | Financials | People

Details

Industries
Biotechnology

Headquarters Regions
Asia-Pacific (APAC)

Founded Date
1993

Founders
Dr. Jing Lou

Operating Status
Active

Last Funding Type
Post-IPO Equity

Legal Name
Sunshine Guojian Pharmaceuticals (Shanghai) Co., Ltd.

Stock Symbol
NASDAQ:SSRX

Company Type
For Profit

Number of Exits
1

Phone Number
+862425386000

3SBio is a fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products primarily in China. Its focus is on addressing large markets with significant unmet medical needs in nephrology, oncology, supportive cancer care, inflammation and infectious diseases.With headquarters and GMP-certified manufacturing facilities in Shenyang, PRC, 3SBio employs over 800 people.

Frequently Asked Questions

Where is **3SBio Inc.**'s headquarters? **3SBio Inc.** is located in **Shenyang, Liaoning, China**.

Who invested in **3SBio Inc.**? **3SBio Inc.** is funded by **Numab**.

How much funding has **3SBio Inc.** raised to date? **3SBio Inc.** has raised **CHF15M**.

When was the last funding round for **3SBio Inc.**? **3SBio Inc.** closed its last funding round on **Dec 12, 2019** from a **Post-IPO Equity** round.

Who are **3SBio Inc.**'s competitors? Alternatives and possible competitors to **3SBio Inc.** may include **Brainsway**, **Innovative Cellular Therapeutics**, and **MabSpace Biosciences**.

Resilience Biotechnologies Inc.

(0 Reviews)

1733 TW Alexander Dr
Durham, NC 27703

Header	Company	Date	News Type
Proposed Initial Public Offering			
Therapure Biopharma Launches Biologics Division as Evolve Biologics, an Innovative Plasma-Derived Therapeutics Company	Evolve Biologics Inc. Resilience Biotechnologies Inc.	2018-03-23	Financial News
Therapure Biopharma Inc. Wins the Mississauga Board of Trade's 2017 Business Awards of Excellence	Resilience Biotechnologies Inc.	2017-11-17	Other Company News
Therapure Biopharma Inc. Ranks No. 115 on the 2017 PROFIT 500 – Its 4th Consecutive Year on the List	Resilience Biotechnologies Inc.	2017-09-27	Other Company News
3SBio Accelerates Expansion of Its Global Biologics Platform by Acquiring the Canadian Biomanufacturing Business of Therapure	3SBio Inc. CPE Funds Resilience Biotechnologies Inc.	2017-09-03	Financial News
Therapure Biomanufacturing Receives 2017 CMO Leadership Individual Attribute Awards for Capabilities and Staff Characteristics	Resilience Biotechnologies Inc.	2017-04-05	Other Company News
For a Third Consecutive Year Therapure Biopharma Inc. Ranks in the PROFIT 500 List of the Fastest-Growing Companies in Canada and Ranks 10th in the GTA Manufacturing Sector	Resilience Biotechnologies Inc.	2016-09-30	Other Company News

Company News

Company Resilience Biotechnologies Inc.

Company News

Header	Company	Date	News Type
	Centre for Commercialization of Regenerative Medicine adMare BioInnovations CoVaRR-Net Cyclica Inc. Cytiva		
U of T Home to New Hub That Will Strengthen Canada's Pandemic Preparedness and Increase Biomanufacturing Capacity	National Research Council Canada Providence Therapeutics Holdings Inc. Resilience Biotechnologies Inc. Sanofi SA Sartorius Stedim Biotech S.A. University of Saskatchewan University of Toronto	2023-03-02	Financial News
Evolve Biologics Announces Site Selection, Land Purchase and Groundbreaking Ceremony for First Manufacturing Facility in Sachse, Texas	Evolve Biologics Inc. National Resilience, Inc. Resilience Biotechnologies Inc.	2021-12-06	Product News
Resilience Receives USD $164 Million Investment From the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness	National Resilience, Inc. Resilience Biotechnologies Inc. Strategic Innovation Fund (SIF)	2021-05-18	Financial News

RESILIENCE GOVERNMENT SERVICES, INC BRANCH

Company Number	F16440265
Status	Incorporated
Incorporation Date	31 March 2015 (over 8 years ago)
Company Type	FOREIGN CORPORATION
Jurisdiction	Maryland (US)
Branch	Branch of OLOGY BIOSERVICES, INC. (Delaware (US))
Registered Address	13200 NW NANO COURT ALACHUA 32615 FL United States
Previous Names	NANOTHERAPEUTICS, INC OLOGY BIOSERVICES, INC
Business Classification Text	03 ORDINARY BUSINESS - STOCK
Agent Name	CSC-LAWYERS INCORPORATING SERVICE
Agent Address	CSC-LAWYERS INCORPORATING SERVICE, COMPANY, 7 ST. PAUL STREET, SUITE 820, BALTIMORE, MD, 21202
Directors / Officers	CSC-LAWYERS INCORPORATING SERVICE, agent
Registry Page	https://egov.maryland.gov/BusinessExp...

Recent filings for RESILIENCE GOVERNMENT SERVICES, INC

Latest Events

- **2022-05-01 - 2022-05-31** Change of name from 'OLOGY BIOSERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC.'
- **2022-09-01 - 2022-09-30** Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'
- **2022-09-01 - 2022-09-30** Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'

See all events

Corporate Grouping USER CONTRIBUTED

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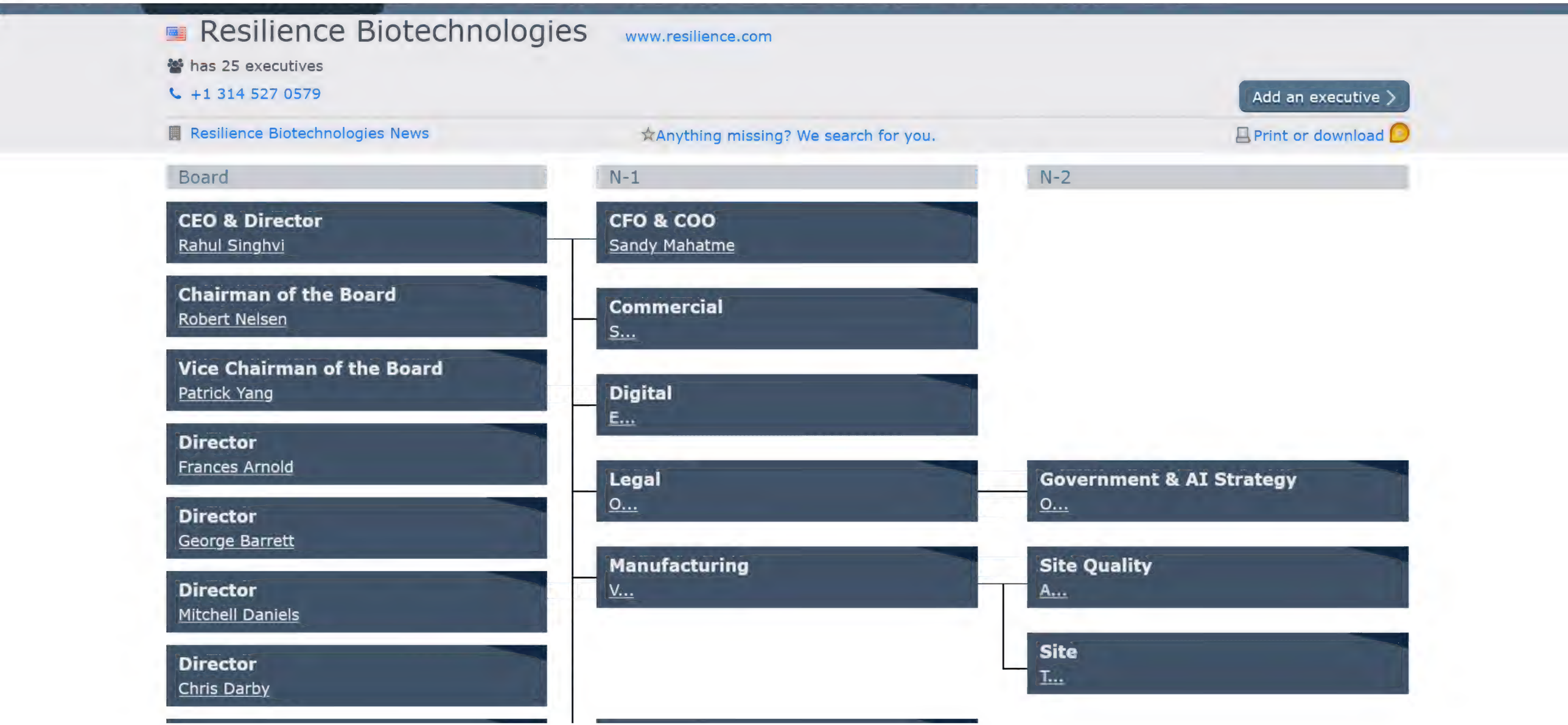
Similarly named companies

branch **RESILIENCE GOVERNMENT SERVICES, INC.** *(Florida (US), 19 Jun 2009-)*

branch **RESILIENCE GOVERNMENT SERVICES, INC.** *(California (US), 22 Mar 2017-)*

Links:

https://www.theofficialboard.com/org-chart/resilience-biotechnologies



CISA CYBERSECURITY ADVISORY COMMITTEE

REPORT TO THE CISA DIRECTOR

Technical Advisory Council

Vulnerability Discovery and Disclosure Recommendations

June 22, 2022

Introduction:

The Technical Advisory Council Subcommittee was established to leverage the imagination, ing
technical experts from diverse background and experiences for the good of the nation. The sub
to evaluate and make recommendations tactical and strategic in nature. These Cybersecurity A
(CSAC) recommendations for the June Quarterly Meeting focus on vulnerability discovery and d

CSAC conducted interviews with sector-specific agencies such as the Food and Drug Administrati
vendors, and CISA staff to determine the current state of vulnerability discovery and disclosure pr
government and industry and provide meaningful recommendations

CISA CYBERSECURITY ADVISORY COMMITTEE

Acknowledgements:

Technical Advisory Council Members:

Mr. Jeff Moss, Subcommittee Chair, DEF CON Communications

Mr. Dino Dai Zovi, Security Researcher

Mr. Luiz Eduardo, Aruba Threat Labs

Mr. Isiah Jones, National Resilience Inc.

Mr. Kurt Opsahl, Electronic Frontier Foundation

Former Members of the Board of Directors

Head of OWS, Moncef Slaoui was also a Board of Directors for Lonza who like Resilience manufactured the Moderna C19 vaccine.

Dr Moncef Slaoui

Independent member of the Board of Directors of Lonza Group Ltd (April 2020 until May 2020)

Dr Moncef Slaoui brings to Lonza extensive experience from his career with GlaxoSmithKline spanning nearly 30 years. In this time, he held a number of leadership positions, including Member of the Board of GSK PLC, Chairman of Pharmaceutical R&D; and Chairman of Global Vaccines. Currently, Dr Slaoui is partner at Medicxi, a venture capital firm specializing in seed, Series A, early stage and late stage life sciences investments; he also sits on various biotechnology companies' boards. Dr Slaoui received his Ph.D. in Molecular Biology and Immunology from Brussels University in 1983. He later received an accelerated Master of Business Administration from IMD in Lausanne (Switzerland) in 1998.

Current activities and functions

Further Mandates:

- Chairman of Monopteros (A Medicxi Company) (since 2018)
- Chairman of Divide & Conquer (A Medicxi Company) (since 2017)
- Chairman of Sutrovax (since 2017)
- Chairman Galvani Bioelectronics (since 2016)
- Chairman of Clasado (since 2017)

Activity:

- Partner at Medicxi (since 2017)

Former activities and functions

- Independent Member of the Board of Directors of Moderna (2017–2020)
- Member of the Advisory Board of the Qatar Foundation (2009–2020)
- Member of the Board of Directors of International AIDS Vaccines Initiatives (2015–2017)
- Member of the Board of GSK PLC (2006–2017)
- Chairman, Global Vaccines of GSK PLC (2009–2017)
- Chairman, Global Research & Development of GSK PLC (2006–2015)
- Various leadership roles in Research & Development including Worldwide Business Development & External Alliances (1988–2003)

Chris Elias
President, Global Development at Bill & Melinda Gates Foundation

Experience

President, Global Development
Bill & Melinda Gates Foundation
Feb 2012 - Present · 11 yrs 6 mos

The Bill & Melinda Gates Foundation's Global Development Division works to identify and fund high-impact solutions that can help hundreds of millions of people lift themselves out of ...see more

President and CEO
PATH
2000 - Jan 2012 · 12 yrs 1 mo

For more than a decade, I served as president and CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world. At PATH, I ex ...see more

Senior Associate, International Programs
Population Council
1990 - 2000 · 10 yrs

As a senior associate, I oversaw all Population Council activities in Thailand, Cambodia, Myanmar, Yunnan, and the Lao PDR, encompassing reproductive health programs, interventions res ...see more

Interests

Top Voices | Companies | Schools

Peter Sands · 3rd
Executive Director at The Global Fund to Fight AIDS, Tuberculosis and Malaria

Bill Gates
Co-chair, Bill & Melinda Gates Foundation
34,786,737 followers

Christopher Elias

President, Global Development Programs, Gates Foundation

Featured on: April 17, 2015

Dr. Elias has been in this role since 2011. He is responsible for all activities outside of the U.S. that are not focused on new medicine development Dr. Elias oversees Global Development's portfolio in Agriculture Development; Family Planning; Financial Services for the Poor; Maternal, Newborn, & Child Health; Polio; Vaccines Delivery; Water, Sanitation & Hygiene; and Special Initiatives. Previously he served as President/CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. Elias currently serves on various advisory boards, including the Nike Foundation and the Duke Global Health Institute. Dr. Elias holds an MD from Creighton University, having completed postgraduate training in internal medicine at the University of California San Francisco, and an MPH from the University of Washington. medicine) from Creighton/UCSF, MPH from University of Washington.

Pharmaceutical services firm Resilience debuts, with questions

New company pitches itself as a disruptive engineering services firm in biopharmaceutical manufacturing

by ***Rick Mullin***

November 25, 2020 | A version of this story appeared in **Volume 98, Issue 46**

Resilience, a venture-backed biopharmaceutical manufacturing services firm, has made its debut with an announcement of $800 million in the bank, a roster of highly-accomplished leaders, and an intent to develop “powerful new technologies”

As a first step, Resilience has acquired Therapure Biopharma, a biologics services firm in Mississauga, Ontaro, that observers say has been for sale for 3 years. It also purchased an undisclosed protein-based therapy-manufacturing operation in the US, Resilience CEO Rahul Singhvi says. Both deals were closed in October.

In addition, Singhvi says the firm has laboratory space in place in San Diego and a pending deal for lab space in Boston. The company plans to add two more manufacturing sites to its network in 2022. Resilience plans to establish a network of approximately 10 facilities with expertise in biological drug development, says Singhvi, former CEO of the vaccine maker Novavax.

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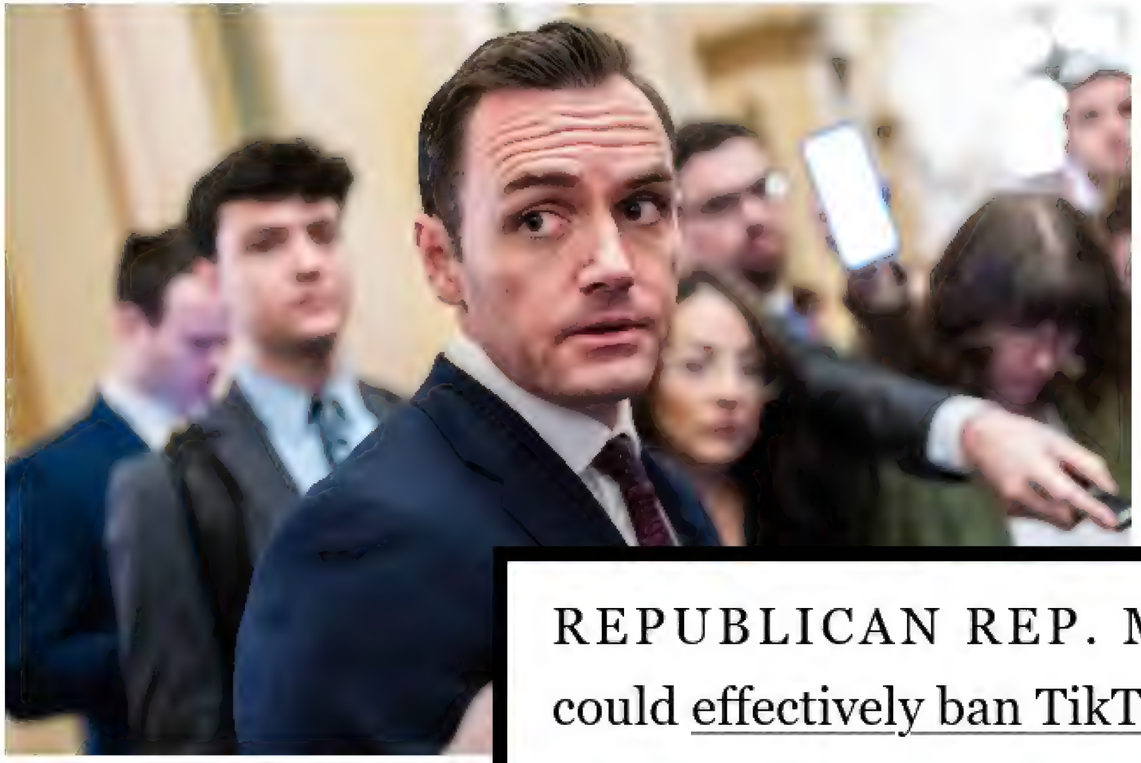
Lawmaker Who Led TikTok Ban Bill Joins Private Surveillance Firm: Report

Mike Gallagher pushed the bill to ban TikTok because China can "surveil its users." Now, he's resigning and joining an American surveillance firm

BY CHARISMA MADARANG, ANDREW PEREZ

MARCH 22, 2024



Rep. Mike Gallagher after House passed act t

WILLIAMS/CQ-ROLL CALL, INC VIA GETTY IMAGES

REPUBLICAN REP. MI

could effectively ban TikTok within the country — on the basis that China can "surveil its users" — plans to take up a post with the American surveillance company and defense contractor Palantir, *Forbes* reported.

REPUBLICAN REP. MIKE Gallagher, who led the charge on a bill that could effectively ban TikTok within the country — on the basis that China can "surveil its users" — plans to take up a post with the American surveillance company and defense contractor Palantir, *Forbes* reported.

https://www.rollingstone.com/politics/politics-news/mike-gallagher-tiktok-ban-palantir-1234993167/

NEWS 06.14.2021

Dr. Stephen Hahn, 24th U.S. FDA Commissioner and former Chief Medical Executive at MD Anderson, joins Flagship Pioneering as Chief Medical Officer of its Preemptive Medicine and Health Security Initiative

Stephen Hahn

Hahn in 2019

24th Commissioner of Food and Drugs

Cambridge, Mass, June 14, 2021 – Flagship Pioneering, the bioplatform innovation company, announced today that Stephen Hahn, M.D. will help lead its Preemptive Medicine and Health Security initiative as Chief Medical Officer, and join Flagship's Senior Leadership Team, effective June 16, 2021. Dr. Hahn served as the U.S. Food and Drug Administration Commissioner from 2019–2021. Prior to joining the FDA, he was the Chief Medical Executive, The University of Texas MD Anderson Cancer Center.

During his time as the 24th Commissioner of the U.S. Food and Drug Administration, Dr. Hahn led the 17,000+ person agency that regulates approximately 20 percent of consumer spending in the United States. He oversaw both COVID and non-COVID regulatory affairs, including therapeutics and vaccine development, devices, diagnostics, and clinical trials.

Stephen Hahn

Article Talk

From Wikipedia, the free encyclopedia

For other people named Stephen Hahn, see Stephen Hahn (disambiguation).

Stephen Michael Hahn (born January 22, 1960) is an American physician who served as the commissioner of food and drugs from 2019 to 2021. Before becoming commissioner, he was an oncologist serving as chief medical executive of the MD Anderson Cancer Center. In 2021, he became chief medical officer at Flagship Pioneering, the venture capital firm that launched Moderna.

https://en.wikipedia.org/wiki/Stephen_Hahn

Receipts

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SOURCES & RECEIPTS

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